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| (51) International Patent Classification 6 : A61B 17/39 | A2 | (11) International Publication Number: WO 97/43971<br>(43) International Publication Date: 27 November 1997 (27.11.97) |

(21) International Application Number: PCT/US97/07818

(22) International Filing Date: 6 May 1997 (06.05.97)

(30) Priority Data:

| | | |
|---|---|---|
| 08/651,796 | 22 May 1996 (22.05.96) | US |
| 08/651,798 | 22 May 1996 (22.05.96) | US |
| 08/663,004 | 7 June 1996 (07.06.96) | US |
| 08/754,588 | 19 November 1996 (19.11.96) | US |
| 08/753,063 | 19 November 1996 (19.11.96) | US |
| 08/752,076 | 19 November 1996 (19.11.96) | US |
| 08/790,081 | 29 January 1997 (29.01.97) | US |
| 08/790,173 | 29 January 1997 (29.01.97) | US |
| 08/790,172 | 29 January 1997 (29.01.97) | US |

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(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

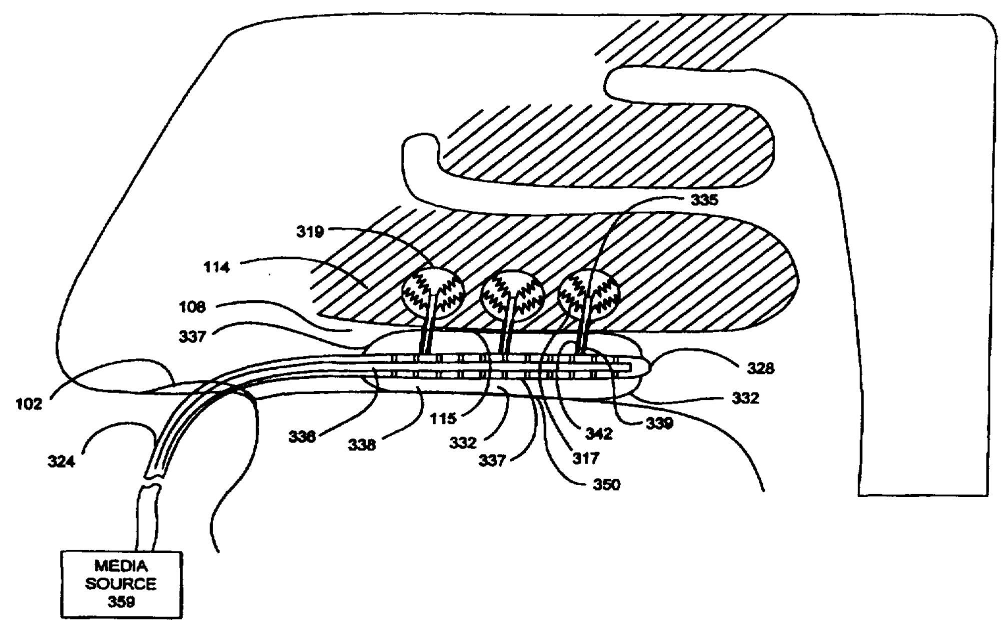
**Published**

*Without international search report and to be republished upon receipt of that report.*

(54) Title: METHOD AND APPARATUS FOR ABLATING TURBINATES

(57) Abstract

A method and apparatus are provided for ablating at least a portion of a nasal concha. By ablating at least a portion of a nasal concha, the size of the nasal concha is reduced. The three nasal concha in the body (inferior, middle and superior nasal concha) form at least a portion of the three nasal meatus (inferior, middle and superior nasal meatus) in the body. By reducing the size of a nasal concha, obstruction of a nasal meatus is reduced or eliminated. As a result, air flow through the nasal meatus is improved. The apparatus includes a catheter with at least one energy delivery device for delivering ablative energy. The method includes positioning the catheter through a nostril of a patient into a nasal meatus adjacent a surface of a nasal concha and delivering sufficient ablative energy from the at least one energy delivery device to the nasal concha to ablate at least a portion of the nasal concha. The energy delivered can be RF, microwave, ultrasound, or laser radiation. The energy is delivered either by probes exiting the catheter and entering the core of the concha, without ablating the surface of the nasal concha, or by other non intruding means. Parameters relevant to the process are tissue impedance, temperature, and amount of energy. An expandable member, inflated by an electrolyte cools the operation site, and allows through its pores the outflow of the electrolyte which can have bioactive, chemoactive or radioactive properties.



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# METHOD AND APPARATUS FOR ABLATING TURBINATES

## FIELD OF THE INVENTION

The present invention relates to a method and apparatus for treating airway obstructions. More specifically, the present invention relates to a method and apparatus for reducing the volume of turbinates in a nasal passageway in order reduce nasal airway obstructions.

## BACKGROUND OF THE INVENTION

Sleep-apnea syndrome is a medical condition characterized by daytime hypersomnomulence, morning arm aches, intellectual deterioration, cardiac arrhythmias, snoring and thrashing during sleep. It is caused by frequent episodes of apnea during the patient's sleep. The syndrome is classically subdivided into two types. One type, termed "central sleep apnea syndrome", is characterized by repeated loss of respiratory effort. The second type, termed obstructive sleep apnea syndrome, is characterized by repeated apneic episodes during sleep resulting from obstruction of the patient's upper airway or that portion of the patient's respiratory tract which is cephalad to, and does not include, the larynx.

Treatments for sleep apnea thus far include various medical, surgical and physical measures to unobstruct the airways. Medical measures include the use of medications such as protriptyline, medroxyprogesterone, acetazolamide, theophylline, nicotine and other medications in addition to avoidance of central nervous system depressants such as sedatives or alcohol. The above medical measures are sometimes helpful but are rarely completely effective. Further, the medications frequently have undesirable side effects.

Surgical interventions have included uvulopalatopharyngoplasty, tonsillectomy, surgery to correct severe retrognathia and tracheostomy.

Other surgical procedures include pulling the tongue as forward as possible and surgically cutting and removing sections of the tongue and other structures which can close off the upper airway passage. These procedures may be effective but the risk of surgery in these patients can be prohibitive and the procedures are often unacceptable to the patients.

Among the air passageways in the body that can become obstructed are the nasal passageways leading from the nose to the pharynx. There are three nasal passageways, namely the inferior, middle and superior nasal meatus. The turbinates, also referred to as nasal concha, are a series of tissues which form at least a portion of these nasal passageways. Forming a portion of the inferior nasal meatus is the inferior nasal concha. The inferior and middle nasal concha each form a portion of the middle nasal meatus. The middle and superior nasal concha each form a portion of the superior nasal meatus. When the inferior, middle and/or superior nasal concha become enlarged, the various nasal meatus which allow air to pass through the nose into the pharynx can become obstructed.

Opening of obstructed nasal airways by reducing the size of the turbinates has been performed using surgical and pharmaceutical treatments. Examples of surgical procedures include anterior and posterior ethmoidectomy, such as those described in "Endoscopic Paranasal Sinus Surgery" by D. Rice and S. Schaefer, Raven Press, 1988); the writings of M. E. Wigand, Messerklinger and Stamberger; and U.S. Patent No. 5,094,233. For example, as described in U.S. Patent No. 5,094,233, the Wigand procedure involves the transection of the middle turbinate, beginning with the posterior aspect, visualization of the sphenoid ostium and opening of the posterior ethmoid cells for subsequent surgery. In the sphenoidectomy step, the ostium of the sphenoid is identified and the anterior wall of the sinus removed. Following this step, the posterior ethmoid cells may be entered at their junction with the sphenoid and the fovea ethmoidalis can be identified as an anatomical landmark for further dissection. In anterior ethmoidectomy, the exenteration of the ethmoids is

carried anteriorly to the frontal recess. Complications, such as hemorrhage, infection, perforation of the fovea ethmoidalis or lamina papyracea, and scarring or adhesion of the middle turbinate, are reported in connection with these procedures.

One of the problems encountered as a result of these procedures is postoperative adhesion occurring between the turbinates and adjacent nasal areas, such as medial adhesion to the septum and lateral adhesion to the lateral nasal wall in the area of the ethmoid sinuses. Otherwise successful surgical procedures may have poor results in these cases. Some surgeons have proposed amputation of a portion of the turbinate at the conclusion of surgery to avoid this complication, resulting in protracted morbidity (crust formation and nasal hygiene problems). The turbinate adhesion problem detracts from these endoscopic surgical procedures. Efforts have been made to reduce the complications associated with the surgical treatment of turbinate tissue, for example by the use of a turbinate sheath device. U.S. Patent No. 5,094,233.

U.S. Patent No. 3,901,241 teaches a cryosurgical instrument which is said to be useful for shrinking nasal turbinates. U.S. Patent No. 3,901,241.

Pharmaceuticals have also been developed for reducing the size of the turbinates. However, pharmaceuticals are not always completely efficacious and generally do not provide a permanent reduction in turbinate size. In addition, pharmaceuticals can have adverse side effects.

A need exists for a method and device for clearing obstructed nasal passageways. It is preferred that the method and device be performable with minimal surgical intervention or post operative complications. It is also preferred that the method and device be performable to reduce the size of the turbinates without involving surgical cutting or the physical removal of tissue. It is also preferred that the method and device provide a permanent reduction in turbinate size.

## SUMMARY OF THE INVENTION

The present invention relates to a method and apparatus for ablating at least a portion of a nasal concha. In one embodiment, the apparatus includes a catheter having a distal portion with a dimension configured for positioning through a nostril of a patient into a nasal meatus adjacent a nasal concha, and an energy delivery device coupled to the catheter distal portion including one or more energy delivering probes extendable from the catheter distal portion a sufficient distance to be inserted into an interior of the nasal concha to deliver ablative energy therein.

In another embodiment, the apparatus includes a catheter having a distal portion with a dimension configured for positioning through a nostril of a patient into a nasal meatus adjacent a nasal concha, the distal portion including an expandable member, expansion of the expandable member within the nasal meatus immobilizing the distal portion within the nasal meatus, and an energy delivery device coupled to the catheter distal portion including one or more energy delivering probes extendable from the catheter distal portion a sufficient distance to be inserted into an interior of the nasal concha to deliver ablative energy therein.

In this embodiment, the expandable member may be designed to conform to a surface of the nasal concha when expanded and/or to a contour of the nasal meatus. In this embodiment, the apparatus may further include a lumen positioned within the catheter for delivering a medium into the expandable member to expand the expandable member and a medium source for delivering the medium through the lumen into the expandable member.

In another embodiment, the apparatus includes a catheter having a distal portion with a dimension configured for positioning through a nostril of a patient into a nasal meatus adjacent a surface of a nasal concha, an energy delivery device coupled to the catheter distal portion including one or more energy delivering probes extendable from the catheter distal portion a sufficient distance to be inserted into an interior of the nasal concha to deliver ablative

energy therein, and an expandable member coupled to the distal portion having a cooling surface, expansion of the expandable member within the nasal meatus placing the cooling surface into contact with a surface of the nasal concha to cool the nasal concha surface.

In this embodiment, the cooling surface preferably provides sufficient cooling to prevent the ablation of the nasal concha surface. The cooling surface may be a microporous membrane through which the medium is delivered. The apparatus may further include a lumen positioned within the catheter for delivering a medium into the expandable member to expand the expandable member adjacent the surface of the nasal concha and a medium source for delivering medium of a sufficiently low temperature to cool the surface of the nasal concha. Expansion of the expandable member may also be used to immobilize the catheter distal end within the nasal meatus. In this embodiment, the expandable member may be designed to conform to a surface of the nasal concha when expanded and/or to a contour of the nasal meatus.

In any of the above embodiments, the one or more energy delivering probes may extend a fixed or variable distance from the catheter distal portion. The one or more energy delivering probes are preferably retractable into the catheter distal portion and extendable from the catheter distal portion. At least two energy delivering probes are preferably included in the energy delivery device. An insulator may be used in combination with the probes to control where energy is delivered. In one variation, the insulator is movable relative to the one or more energy delivering probes.

In any of the above embodiments, the energy delivering probes are adapted to deliver one of a variety of forms of ablative energy including, for example, RF, microwave, ultrasonic, pulsed laser and diffuse laser energy. When delivering RF energy, the probes are preferably needle electrodes. When delivering laser energy, the probes are preferably optical fibers. When delivering microwave energy, the probes preferably include microwave antenna.

When delivering ultrasonic energy, the probes preferably include ultrasound transducers.

In any of the above embodiments, the apparatus may further include at least one sensor coupled to the processor. The sensor may be used to measure a variety of properties, including an amount of energy delivered by the energy delivery device, an amount of heat generated at a location, an amount of impedance generated, and a temperature at a location. The energy delivered to the energy delivery device may also be controlled by the processor in response to a measured property.

In any of the above embodiments, the apparatus may further include an energy source coupled to the energy delivery device for delivering energy to the probes.

In another embodiment of the invention, an apparatus is provided which includes a catheter having a distal portion with a dimension configured for positioning the catheter distal portion through a nostril of a patient into a nasal meatus adjacent a surface of a nasal concha, an expandable member positioned at the catheter distal portion, an energy delivery device positioned at the catheter distal portion for delivering ablative energy to the surface of the nasal concha, and a lumen positioned within the catheter for delivering a medium into the expandable member to expand the expandable member.

In another embodiment of the invention, an apparatus is provided for ablating a selected portion of a nasal concha. In this embodiment, the apparatus includes a catheter having a distal portion with a dimension configured for positioning the catheter distal portion through a nostril of a patient into a nasal meatus adjacent a surface of a nasal concha, an energy delivery device for delivering ablative energy positioned at the catheter distal portion, and an insulator positioned to cause delivery of ablative energy to a selected portion of a nasal concha while insulating other tissue forming the nasal meatus from the ablative energy.

In yet another embodiment of the invention, an apparatus is provided for ablating an internal section of a nasal concha. According to this embodiment, the apparatus includes a catheter having a distal portion with a dimension configured for positioning the catheter distal portion through a nostril of a patient into a nasal meatus adjacent a surface of a nasal concha, an expandable member positioned at the catheter distal portion, an energy delivery device for delivering ablative energy positioned at the catheter distal portion, a lumen positioned within the catheter for delivering a medium into the expandable member to expand the expandable member to adjacent a surface of the nasal concha, and a medium source for delivering medium of a sufficiently low temperature to cool the surface of the nasal concha during energy delivery. According to this embodiment, the energy used should be of a type which can penetrate into an internal section of tissue and cause ablative heating therein. Examples of this type of energy included electromagnetic energy (RF, microwave) and ultrasonic.

A method is provided for ablating at least a portion of a nasal concha. According to one embodiment of the method, a catheter having a distal portion with an expandable member and an energy delivery device for delivering ablative energy is taken and positioned through a nostril of a patient into a nasal meatus adjacent a surface of a nasal concha. The expandable member is then expanded within the nasal meatus so that the expandable member is brought into contact with the surface of the nasal concha. Sufficient ablative energy is then delivered from the energy delivery device to the nasal concha to ablate at least a portion of the nasal concha.

A method is also provided for ablating at least a portion of a nasal concha using a catheter having a distal portion with a dimension configured for positioning through a nostril of a patient into a nasal meatus adjacent a nasal concha and an energy delivery device coupled to the catheter distal portion including one or more energy delivering probes. In the method, the distal portion of the catheter is positioned through a nostril of a patient into a nasal

meatus adjacent a surface of a nasal concha. The one or more energy delivering probes are then introduced into an interior of the nasal concha. Sufficient ablative energy is then delivered into the interior of the nasal concha to ablate at least a portion of the nasal concha. In the method, the nasal concha is preferably the inferior nasal concha and the nasal meatus is preferably the inferior nasal meatus. The portion of the nasal concha ablated is preferably an anterior section of the inferior nasal concha. More preferably, less than one-third of the inferior nasal concha in the anterior portion of the inferior nasal concha is ablated. The nasal concha is preferably reduced in size a sufficient amount to increase the rate of airflow through the nasal meatus at a given pressure by at least 25%.

In one variation of this embodiment, the catheter includes an expandable member coupled to the catheter distal portion. According to this variation, the method further includes the step of expanding the expandable member within the nasal meatus to immobilize the distal portion within the nasal meatus. Expansion of the expandable member may be performed by delivering a medium into the expandable member which may be delivered through a lumen within the catheter into the expandable member. This medium may also be used in the method to cool the surface of the nasal concha during the delivery of energy in order to prevent the surface of the nasal concha from being ablating.

By using the energy delivering probes, delivery of ablative energy can be performed substantially bloodlessly. In addition, by allowing the ablated tissue to be removed by natural absorption, the step of removing the ablated nasal concha tissue is performed substantially bloodlessly and without introducing an element into the nasal concha.

According to the method, ablation of the nasal concha is preferably done without ablating the surface of the nasal concha. Prevention of the surface tissue of the nasal concha from being ablated can be performed by the step of cooling the surface of the nasal concha during the delivery of energy.

A method is also provided for reducing the size of a nasal concha. According to one embodiment of the method, ablative energy is delivered through a surface of the nasal concha to ablate a portion of the nasal concha. According to the method, energy is delivered through the surface of the nasal concha without introducing an element into the nasal concha. Ablated nasal concha tissue is then removed by natural absorption of the ablated tissue by the patient's body.

A method is also provided for reducing the size of a nasal concha without forming an external wound. According to one embodiment of the method, ablative energy is delivered through a surface of the nasal concha without introducing an element into the nasal concha to ablate a portion of the nasal concha. Meanwhile, the surface of the nasal concha is cooled such that a layer of tissue adjacent the nasal concha surface is not ablated. Ablated nasal concha tissue is then removed by natural absorption of the ablated tissue by the patient's body.

## BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates the construction of the nasal passageways of the human nose.

Figure 2 illustrates the effect enlargement of a nasal concha has on a nasal air passageways.

Figures 3A-3D illustrate an embodiment of a method for ablating a nasal concha.

Figure 3A illustrates the introduction of an apparatus through a nostril into a nasal meatus adjacent a surface of a nasal concha.

Figure 3B illustrates the expansion of the expandable member within the nasal meatus so that the energy delivery device is brought into energy communication with the surface of the nasal concha to be treated.

Figure 3C illustrates the delivery of energy to a selected portion of a nasal concha by selecting the placement of the apparatus within the nasal meatus.

Figure 3D illustrates insulating at least a portion of the nasal concha from ablative energy.

Figures 3E-3G illustrate another embodiment of a method for ablating a nasal concha.

Figure 3E illustrates the introduction of an apparatus through a nostril into a nasal meatus adjacent a surface of a nasal concha.

Figure 3F illustrates the extension of an energy delivery device from the apparatus into an interior of the nasal concha and the delivery of energy into the nasal concha.

Figure 3G illustrates the immobilization of the apparatus within the nasal meatus and the cooling of the surface of the nasal concha during the delivery of energy to the nasal concha.

Figures 4A-D illustrate the steps of ablating a portion of a nasal concha according to the present invention.

Figure 4A illustrates the step of introducing ablative energy into an interior section of a nasal concha using a device according to Figures 3A-3D.

Figure 4B illustrates the step of introducing ablative energy into an interior section of a nasal concha using a device according to Figures 3E-3G.

Figure 4C illustrates an ablated tissue region and its absorption by the body.

Figure 4D illustrates the resulting reduction in the size of the nasal concha.

Figure 5 illustrates an apparatus according to the present invention.

Figure 6 illustrates the use of a plurality of ring electrodes in an apparatus according to the present invention.

Figure 7 illustrates an apparatus which includes an insulator for selectively delivering ablative energy to a desired section of a nasal concha.

Figure 8 illustrates an apparatus according to the present invention.

Figure 9 illustrates an apparatus according to the present invention with an expandable member for immobilizing the apparatus within a nasal meatus.

Figure 10 is a block diagram of a feedback control system useful with the method and apparatus of the present invention.

Figure 11 is a block diagram illustrating an analog amplifier, analog multiplexer and microprocessor used with the feedback control system of Figure 10.

Figure 12 is a block diagram of a temperature/impedance feedback system that can be used to control cooling medium flow rate through an apparatus of the present invention.

Figure 13 shows an electrode for ablating tissue.

Figure 14 shows a cross section of an electrode for ablating tissue.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention provides a method and apparatus for ablating at least a portion of a nasal concha (turbinate). By ablating at least a portion of a nasal concha, the size of the nasal concha can be reduced. Accordingly, the present invention also provides a method for reducing the size of a nasal concha. The three nasal concha in the body (inferior, middle and superior nasal concha) form at least a portion of three nasal meatus (inferior, middle and superior nasal meatus). By reducing the size of a nasal concha, obstruction of a nasal meatus can be reduced. By reducing an obstruction of a nasal meatus, air flow through the nasal meatus is improved. Accordingly, the present invention also relates to a method for improving airflow through a nasal meatus of the body.

Figure 1 illustrates the construction of the nasal passageways of the human nose 100. As illustrated in the figure, the human nose includes a nostril 102 which leads into the nasal passageways from outside the body and a nasopharyngeal opening 104 which leads into the nasal passageways from the pharynx 106. Connecting the nostril 102 and nasopharyngeal opening 104 are a

series of passageways, namely the inferior nasal meatus 108, the middle nasal meatus 110, and the superior nasal meatus 112. Forming at least a portion of each of these passageways are the nasal concha, also referred to as the turbinates. Forming at least a portion of the inferior nasal meatus 108 is the inferior nasal concha 114. Forming at least a portion of the middle nasal meatus 110 is the inferior nasal concha 114 and the middle nasal concha 116. Forming at least a portion of the superior nasal meatus 112 is the middle nasal concha 116 and the superior nasal concha 118. As also shown in Figure 1, the inferior nasal concha 114 includes an anterior portion 120 which terminates adjacent the nasopharyngeal opening 104 and a posterior portion 122 which terminates adjacent the nostril 102.

Ablation of a nasal concha is accomplished according to the present invention by physically introducing an energy delivery device into an interior section of nasal concha tissue to deliver ablative energy therein. In the method and apparatus, the energy delivery device is designed to be minimally invasive such that the energy delivery device is introduced into the nasal concha without significantly injuring the surface of the nasal concha (aside from where the energy delivery device enters the nasal concha). For example, narrow bore needle-shaped probes for delivering energy may be used in the energy delivery device for insertion into the nasal concha.

The use of energy delivered by a minimally invasive means to ablate interior nasal concha tissue eliminates the need for surgical cutting to remove a portion of a nasal concha and the risks associated therewith. In particular, the procedure can be performed substantially bloodlessly and without having to expose tissue interior to the nasal concha, thereby significantly reducing the risk of infection.

Ablation can also be performed to remove an internal portion of the nasal concha without injuring the surface of the nasal concha (aside from where the energy delivery device enters the nasal concha). For example, by inserting the energy delivery device into the interior of the nasal concha and delivering

energy to the nasal concha away from the surface of the nasal concha, interior tissue of the nasal concha can be ablated without simultaneously ablating the surface of the nasal concha. Cooling of the surface of the nasal concha may also be performed to prevent ablation of the surface of the nasal concha. As a result, the present invention provides a method and apparatus for reducing the size of a nasal concha without significantly injuring the surface of the nasal concha. By avoiding injury to the surface of the nasal concha, use of the apparatus of the present invention should be significantly less painful to the patient than traditional surgical methods for removing nasal concha tissue.

According to the present invention, it is preferred to ablate the inferior nasal concha 114, and more preferably an anterior portion 120 of the inferior nasal concha 114. In a preferred embodiment, the anterior portion 120 of the inferior nasal concha 114 is defined as being no larger than about one-third the volume of the inferior nasal concha 114. Thus, in one embodiment, the method includes ablating no more than about one-third of the inferior nasal concha 114.

Figure 2 illustrates the effect enlargement of a nasal concha has on a nasal air passageway. As shown in Figure 2, enlargement of the inferior nasal concha 114 can result in an obstruction of inferior nasal meatus 108. By reducing the size of the inferior nasal concha 114, illustrated in Figure 2 by region below dashed line 123, the inferior nasal meatus 108 is reopened.

I. Method For Turbinate Ablation

One aspect of the present invention relates to a method for ablating nasal concha tissue. Figures 3A-3D illustrate an embodiment of this method. As shown in Figure 3A, an apparatus 124 having a distal portion 128 with an expandable member 132 and an energy delivery device 134 for delivering ablative energy is introduced through a nostril 102 into a nasal meatus adjacent a surface of a nasal concha, shown in the figure as the inferior nasal meatus 108 and the inferior nasal concha 114.

As shown in Figure 3B, the expandable member 132 is expanded within the nasal meatus 108 so that the expandable member 132 is brought into

contact with the surface 115 of the nasal concha 114 to be treated. Ablative energy 117 is then delivered through the apparatus and the energy delivery device 134 to the nasal concha 114. Sufficient energy 117 is delivered through the surface 115 of the nasal concha 114 to ablate at least a portion 119 of the nasal concha 114.

According to this method, the ablative energy may be any form of energy capable of causing the ablation of tissue by heating at least a portion of the nasal concha being treated to a temperature above about 40 °C. Examples of types of energy that may be used include, but are not limited to energy from a diode laser ablation, a laser fiber (defused), microwave (915 MHz and 2.45 GHz), ultrasound, and RF at all relevant frequencies. In a preferred embodiment, the energy is electromagnetic energy and is preferably RF radiation or microwave radiation.

When the energy is RF radiation, the energy preferably has a frequency between about 300 megahertz and about 700 megahertz. The RF energy delivered to the nasal concha is preferably sufficient to deliver between about 5 and about 30 watts of RF energy to at least a portion of the nasal concha being treated.

According to this method, the expandable member is preferably expanded by delivering a medium into the expandable member. Figure 3C illustrates the delivery of the medium 138 through a lumen 135 within the distal portion of the apparatus into the expandable member 132 to expand the expandable member 132. The electrolytic medium 138 exits the lumen 135 through apertures 137 in the lumen wall. Accordingly, a further step of the method includes expanding the expandable member by delivering a medium into the member.

The medium may be any media capable of conducting energy from the energy delivery device to the nasal concha to be ablated. The medium can be a fluid or a gel. When RF energy is used, the medium is preferably a dielectric substance, such as saline, which aids the delivery of energy, referred to herein as

an electrolytic medium. In one particular embodiment, the electrolytic medium is saline formed from distilled water with a NaCl content of less than about 10% by weight. The medium can also include a variety of substances known in the art for providing a bioactive, chemoactive, or radioactive effect desirable in conjunction with the ablation of turbinates. Examples of such substances include ablative acidic or alkaline substances, antibiotics, chemotherapeutic agents, a fluorescent or radioactive dye or marker, or some combination thereof.

As illustrated in Figure 3D, an insulative covering 142 may be positioned over a portion of the expandable member 132 to control the delivery of energy to a selected section of tissue. Accordingly, a further step of the method includes delivering energy to at least a portion of a nasal concha while insulating at least a portion of the tissue forming the nasal meatus from the energy being delivered to the nasal concha.

Figures 3E-3G illustrate another embodiment of this method. As shown in Figure 3E, an apparatus 324 having a distal portion 328 and an energy delivery device 334 for delivering ablative energy is introduced through a nostril 102 of a patient and into a nasal meatus adjacent a surface of a nasal concha, shown in Figures 3E-3G as the inferior nasal meatus 108 and the inferior nasal concha 114.

The energy delivery device 334 shown in the figures includes three probes 139 for delivering ablative energy. These probes are preferably contained within the distal portion 328 of the apparatus during introduction into the nasal meatus and are extended from the distal portion 328 after introduction.

As illustrated in Figure 3F, the probes 339 are delivered through the surface 115 of the nasal concha 114 and into an interior section of the nasal concha. The apparatus may be designed such that the probes of the energy delivery device 334 extend a fixed length from the apparatus. Alternatively, as illustrated in Figure 3G by arrow (↔), the energy delivery device 334 may be designed to be at least partially extendable from the distal portion 328 and/or at least partially retractable into the distal portion 328.

Once the probes 339 of the energy delivery device 334 are positioned within the nasal concha, ablative energy 317 is delivered through the apparatus and the energy delivery device 334 to an area 319 of the nasal concha 114 adjacent the probes 339. Sufficient energy 317 is delivered during this step to ablate at least a portion of the nasal concha 114.

According to this embodiment of the method, the ablative energy may be any form of energy capable of causing the ablation of tissue by heating at least a portion of the nasal concha being treated to a temperature above about 40 °C. Examples of types of energy that may be used include, but are not limited to energy from a diode laser ablation, a laser fiber (defused), microwave (915 MHz and 2.45 GHz), ultrasound, and RF at all relevant frequencies. In a preferred embodiment, the energy is electromagnetic energy and is preferably RF radiation or microwave radiation. Illustrated in Figure 3F are a series of RF electrodes 339 as the energy delivery device 334. The invention is also intended to encompass the use of probes designed to deliver different forms of energy.

When the energy used is RF radiation, the energy preferably has a frequency between about 300 megahertz and about 700 megahertz. The RF energy delivered to the nasal concha is preferably sufficient to deliver between about 5 and about 30 watts of RF energy to at least a portion of the nasal concha being treated.

The apparatus of the present invention may be designed to be immobilized within the nasal meatus. This may be accomplished, for example, by including an expandable member on the apparatus distal portion 328, illustrated in Figure 3G and Figure 8 as element 332. When expanded within the nasal meatus 108, the expandable member 332 serves to immobilize the apparatus distal portion 328 relative to the nasal concha 114 to be ablated. Accordingly, the method may optionally further include the step of immobilizing the apparatus distal portion relative to the nasal concha. Further, when the apparatus includes an expandable member, the step of immobilizing

the apparatus within the nasal meatus may include the step of expanding the expandable member within the nasal meatus.

In any of the above variations of this embodiment, the surface 115 of the nasal concha 114 may also be cooled during the delivery of energy. Cooling the surface 115 of the nasal concha 114 may be accomplished, for example, by cooling the distal portion of the apparatus within the nasal meatus. As illustrated in Figure 3G, the apparatus may include an expandable member 332 attached to the apparatus at the distal portion 328. In this embodiment, the apparatus also includes a lumen 336 coupled to the apparatus for delivering a medium 338 through apertures 337 in the lumen 136 to expand the expandable member 332. The medium is delivered from a media source 359 through the lumen 336 to within the expandable member 332. During ablation, cool media may be delivered from the media source 359 into the expandable member to cool the surface 115 of the nasal concha.

Cooling the surface of the nasal concha being treated with energy serves at least two purposes. Cooling may be used to prevent ablation of the surface 115 of the nasal concha 114 by preventing the surface 115 from reaching a temperature at which the tissue becomes ablated. In this regard, it is preferred that the cooling be sufficient to prevent the surface tissue of the nasal concha from exceeding a temperature of about 40 °C.

Cooling may also be used to control the location of the ablation site. For example, cooling the nasal concha surface enables the formation of an entirely internal ablation site. The extent of cooling provided, in combination with the positioning of the energy delivery device 334 and the amount of energy delivered, can be used to control the thickness of non-ablated tissue between the surface of the nasal concha and the internal ablation site.

According to this embodiment of the method, the nasal meatus into which the apparatus is delivered may be the inferior, middle and/or superior nasal meatus and is preferably the inferior nasal meatus. The nasal concha ablated may be the inferior, middle and/or superior nasal concha and is

preferably the inferior nasal concha. In one embodiment, energy is delivered to a selected section of one of the nasal concha. For example, energy may be selectively delivered to the anterior or posterior sections of the inferior nasal concha. Delivery of energy to a selected section of a nasal concha may be accomplished by the placement of the apparatus within the nasal meatus. The delivery of energy to a selected section of a nasal concha may also be accomplished by insulating at least a portion of the nasal concha from ablative energy.

As also illustrated in Figure 3G, an insulative covering 342 may be positioned over a portion of the energy delivery device 334 to control the delivery of energy to a selected section of tissue. The positioning of the insulative covering 342 may be adjustable relative to the energy delivery device 334. Accordingly, the method may optionally include the further step of delivering energy to a portion of a nasal concha while insulating another portion of the nasal concha. The method may also optionally include the step of adjusting the position of the insulating covering 342 relative to the energy delivery device 134.

The present invention also relates to a method for reducing the size of a nasal concha. According to the method, the size of a nasal concha is reduced by ablating tissue forming a nasal concha and removing the ablated nasal concha tissue. Removal of the ablated nasal concha tissue is preferably accomplished by natural absorption of ablated tissue by the patient's body.

Figures 4A-D illustrate the removal of an internal region of tissue by ablation. Figure 4A illustrates introducing ablative energy 117 into an interior section 144 of a nasal concha through the surface of the nasal concha using a device as illustrated in Figures 3A-D. Figure 4B illustrates introducing ablative energy 317 via energy delivery device probes 339 into an interior section 344 of a nasal concha 114 using a device as illustrated in Figures 3E-G. Cooling of the surface 115 of the nasal concha 114 may be performed in order to prevent the ablation of the surface of the nasal concha.

Figure 4C illustrates the absorption (illustrated by arrows 148) of a region 146 of ablated tissue by the body. As illustrated in Figure 4C, the ablated tissue region 146 is an interior region, i.e., the surface 115 of the nasal concha is not ablated. This may be achieved by cooling the surface 115 of the nasal concha during the delivery of ablative energy to the nasal concha. It may also be achieved by controlling the positioning of the energy delivery device 134 relative to the surface 115 and by controlling the amount of energy delivered by the energy delivery device 134.

Figure 4D illustrates the resulting reduction in the size of the nasal concha after absorption. Region 149 illustrates the volume of tissue that is removed from the path of the nasal meatus by this method. As can be seen by comparing Figures 4A or 4B to 4D, the size of nasal meatus 108 is enlarged by this process.

The present invention also relates to a method for improving airflow through a nasal meatus by reducing the size of a nasal concha which defines at least a portion of the nasal meatus. This method can be accomplished by the method for reducing the size of a nasal concha as described above. In one embodiment, the rate of airflow through the nasal meatus at a given pressure is increased by at least 25%.

## 2. Turbinate Ablation Apparatus

The present invention also relates to an apparatus for ablating a nasal concha. As illustrated in Figure 5, the apparatus 124 includes a catheter body 126 which has a distal portion 128 with dimensions configured for introduction through a nostril of a patient into a nasal meatus of a patient.

An expandable member 132 is attached to the catheter body 126 at the catheter distal portion 128. Also attached to the catheter body 126 at the catheter distal portion 128 is an energy delivery device 134 for delivering ablative energy.

According to the present invention, the expandable member preferably conforms to the surface of the nasal concha to be ablated when the expandable member is expanded. A variety of mechanisms known in the art may be used to expand the expandable member. One mechanism, illustrated in Figure 5, involves the use of a lumen 136 coupled with the catheter body 126 for delivering a medium 138 to expand the expandable member 132. The medium is delivered from a media source 159 through the lumen 136 to within the expandable member 132 through apertures 137. The apertures 137 may be formed by a sheath 150 which substantially surrounds the lumen 136. In one embodiment, the sheath 150 is formed of a relatively inert and relatively hard substance, such as metallic copper or metallic silver. In alternative embodiments, the sheath 150 includes some other inert substance, such as gold, stainless steel, titanium, various plastic compounds, or some combination thereof.

The sheath preferably has a traverse diameter of about 6 french. (about 0.090 inches). However, it should be understood that the sheath may have a variety of thicknesses. The sheath 150 also preferably has a thickness of about 0.001 inches. This embodiment is particularly preferred in the case when the sheath is copper.

The medium used to expand the expandable member is preferably an electrolytic medium, i.e., a medium which is capable of conducting electromagnetic energy and can be used to convey energy from the energy delivery device to the nasal concha to be ablated.

The expandable member is preferably formed of a material which is permeable to the electrolytic medium used to expand the member. By selecting the material used to form the expandable member such that it is permeable to the electrolytic medium, the electrolytic medium is able to pass through the expandable member to the surface of the nasal concha being ablated during operation of the apparatus. In one embodiment, the expandable member is an expandable porous membrane.

As illustrated in Figure 5, the energy delivery device 134 may be positioned within the expandable member. This energy delivery device may be a needle electrode or a conductive film lining the outside of the lumen. The sheath may also serve as the energy delivery device. Alternatively, the energy delivery device may be positioned on a surface 147 of the expandable member. The energy delivery device may be a single energy delivery device or may include a plurality of energy delivery devices where energy is independently deliverable to each energy delivery device.

In one embodiment, illustrated in Figure 6, the energy delivery device includes one or more ring electrodes 156 disposed on the surface of the expandable member 132. As illustrated, the plurality of ring electrodes 156 may be disposed in parallel with their axes aligned with a long axis 160 of the catheter body 126. As noted above, energy may be delivered to all of the energy delivery devices or may be independently delivered to each energy delivery device.

In another embodiment, a plurality of energy delivery devices are positioned on a surface of the expandable member. An example of a suitable surface for disposition on the membrane is described in Application Serial No. 08/319,373, "Thin Layer Ablation Apparatus", filed October 6, 1994, which is incorporated by reference. It is noted that a combination of ring electrodes and surface energy delivery devices may be used.

In a further embodiment of the invention, illustrated in Figure 7, the apparatus includes an insulator 162 which prevents the delivery of ablative energy 117 through at least a portion of the expandable member. As illustrated in Figure 7, the insulator 162 may be positioned over the surface 147 of the expandable member 132. Using the insulator 162, ablative energy can be delivered to a selected section of a nasal concha 153 while preventing the ablation of another selected section of tissue 155. For example, ablative energy can be selectively delivered to a nasal concha forming at least a portion of the

nasal meatus. Meanwhile, the insulator can be used to prevent the ablation of other portions of the nasal meatus.

Another embodiment of the invention, the apparatus includes a plurality of probes, as illustrated in Figure 8, which form the energy delivery device 334. The energy delivery device 334 is illustrated in the figure as including a plurality of probes 339 designed to pierce the nasal concha and deliver ablative energy therein. In order to facilitate the entry of the probes into the nasal concha, each probe preferably includes a pointed distal end 335.

The probes 339 of the energy delivery device 334 may extend a fixed distance from the catheter distal portion 328. In such case, the probes 139 should extend from the catheter distal portion 328 a sufficient distance necessary to ablate an interior portion of the nasal concha 114. Alternatively, as illustrated in Figure 8 by the arrow (↔), the energy delivery device 334 may be designed to be at least partially extendable from the catheter distal portion 328 and/or at least partially retractable into the catheter distal portion 328.

The energy delivery device 334 should also be configured to selectively introduce the probes into the nasal concha or a selected subregion of the nasal concha. Accordingly, when a plurality of probes 339 are used as illustrated in Figure 8. the probes should be positioned relative to the catheter distal portion 328 so that the probes 339 are all introduced into the nasal concha and not into other tissue adjacent the nasal concha.

The probes 339 used in the energy delivery device 334 may be any probe which can pierce the surface of a nasal concha and which can deliver a form of energy capable of causing the ablation of tissue. Ablation is preferably performed by heating at least a portion of the nasal concha to be treated to a temperature above about 40 °C. Examples of types of energy that may be used include, but are not limited to energy from a diode laser ablation, a laser fiber (defused). microwave (915 MHz and 2.45 GHz), ultrasound. and RF at all relevant frequencies. In a preferred embodiment, the energy is electromagnetic

energy and is preferably RF radiation or microwave radiation delivered into the nasal concha by one or more needle electrodes.

When the energy is RF radiation, the energy preferably has a frequency between about 300 megahertz and about 700 megahertz. The RF energy delivered to the nasal concha is preferably sufficient to deliver between about 5 and about 30 watts of RF energy to at least a portion of the nasal concha being treated.

As illustrated in Figure 8, the energy delivery device may optionally include an insulator 362 surrounding each probe 339 which prevents the delivery of ablative energy 317 through at least a portion of the probe 339. As illustrated in Figure 8, by the dashed lines 361, the insulator 362 may be moved relative to the energy delivery device 334 to cause energy to be delivered to a selected section of a nasal concha while preventing the ablation of another selected section of tissue.

As illustrated in Figure 9, an expandable member 332 may be attached to the catheter 326 at the catheter distal portion 328. The expandable member can be used to immobilize the catheter distal portion 328 within the nasal meatus by expanding against the walls forming the nasal meatus. The expandable member preferably conforms to a contour of the nasal meatus when expanded. In one embodiment, the expandable member conforms to the surface of the nasal concha when expanded.

A variety of mechanisms are known in the art which may be used to expand the expandable member 332. One mechanism, illustrated in Figure 9, involves the use of a lumen 336 coupled with the catheter 326 for delivering a medium 338 to expand the expandable member 332. The medium is delivered from a media source 359 through the lumen 336 to within the expandable member 332 through apertures 337. The apertures 337 may be formed by a sheath 350 which substantially surrounds the lumen 336. In one embodiment, the sheath 350 is formed of a relatively inert and relatively hard substance, such as metallic copper or metallic silver. In alternative embodiments, the sheath 350

includes some other inert substance, such as gold, stainless steel, titanium, various plastic compounds, or some combination thereof.

The expandable member illustrated in Figure 9 can also be used to cool the surface of a nasal concha being ablated. Cooling may be accomplished by introducing cool medium into the expandable member. This may be accomplished, for example, by including a cooling mechanism into the media source 359 to cool the media.

As illustrated in Figures 5 and 8, ablative energy is supplied to the energy delivery device by an energy source. As discussed above, a variety of forms of ablative energy may be used in the present invention. Accordingly, the energy source is selected to provide the desired form of energy. The energy used is preferably RF energy which ablates the turbinate by heat and cell destruction.

In one embodiment, the energy source includes an energy source 163 (or a power regulator coupled to a standard energy source such as a wall socket or battery), a signal generator 165 (such as a generator for pulses, sine waves, square waves, or some combination of these wave forms with each other or with some other wave form), and a processor 167 for controlling the signal generator.

In a preferred embodiment, the signal generator generates pulses of RF energy having an RF radiation frequency between about 300 megahertz and about 700 megahertz, such as preferably about 465 megahertz. In alternative embodiments, the RF energy may have an RF radiation frequency in the microwave range or in another range of the electromagnetic spectrum.

The processor controls the amount of energy delivered by the apparatus. In this embodiment, the apparatus can further include a signal generator coupled to the energy delivery device and coupled to a energy source. The apparatus can also include a processor coupled to the signal generator and disposed for controlling the signal generator. According to this embodiment, the processor can control the way in which energy is delivered. For example, the signal generator can generate pulses of RF energy which provide between

about 5 watts and about 30 watts of RF energy to at least a portion of the turbinate. The processor can also control the amount of energy produced so that the region of turbinate tissue to be ablated is heated to a temperature of at least 40 °C.

In order to monitor the amount of energy delivered and the amount of heat generated, the apparatus can also include one or more sensors. These sensors can be used to detect a variety of operating parameters including the amount of energy delivered, the impedance generated, and the temperature of a region adjacent the apparatus. These sensors can also be used to provide feedback for controlling the operation of an energy source which delivers energy to the energy delivery device. In addition, chemical or biochemical sensors can be used to detect ablation.

In one embodiment, the apparatus includes at least one temperature sensor, such as a thermocouple or thermistor. The temperature sensor is coupled to a communication link (such as a conductor), which is coupled to the processor. For example, in the case where the temperature sensor is a thermocouple, the communication link may comprise a D/A converter coupled to a register disposed for reading by the processor. The processor reads an sensor value from the sensor and, responsive thereto, controls the signal generator so as to achieve delivery of an effective amount of RF energy to a desired section of tissue to be ablated. The processor thus uses the signal generator, catheter distal portion, energy delivery device, and temperature sensor, as a feedback loop for controlled delivery of RF energy to a section of a nasal concha. For example, the processor may control the delivery of RF energy to achieve delivery of a selected amount of energy, to achieve a selected temperature, or to achieve a selected amount of ablation of a section of a nasal concha. A variety of positionings for the sensors are possible. In one embodiment, the sensor is coupled to the expandable member.

As described above, the temperature or some other property of the tissue being ablated, or of the energy delivery device can be monitored using a

variety of sensors. Illustrated in Figures 10 and 11 is an open and a closed loop feedback system for coupling a sensor used in the apparatus to an energy source so that the output energy of the energy source is adjusted in relation to the property sensed by the sensor. The feedback system, is described herein with regard to the delivery of RF energy. It should be noted, however, that the feedback system can be readily adjusted for use with a variety of other types of energy, such as microwaves.

Using the feedback system, the physician can, if desired, override the closed or open loop system. A microprocessor can be included and incorporated in the closed or open loop system to switch energy on and off, as well as modulate the energy. The closed loop system utilizes a microprocessor to serve as a controller, watch the temperature, adjust the amount of energy being delivered, look at the result, re-feed the result, and then modulate the energy.

In the case of RF energy, the sensors and feedback control system can be used to maintained tissue adjacent to an energy delivery device at a desired temperature for a selected period of time without impeding out. An output maintains the energy delivered to the energy delivery device for a selected length of time.

As illustrated in Figure 10, current is delivered through energy delivery device 189 is measured by current sensor 190. Voltage is measured by voltage sensor 192. Impedance and energy are then calculated at energy and impedance calculation device 194. These values can then be displayed at a user interface and display 196. Signals representative of energy and impedance values are received by a controller 198.

A control signal is generated by controller 198 that is proportional to the difference between an actual measured value, and a desired value. The control signal is used by energy circuits 200 to adjust the energy output in an appropriate amount in order to maintain the desired energy delivered at each energy delivery device 189.

In a similar manner, temperatures detected at temperature sensors 191 provide feedback for maintaining a selected energy. The actual temperatures are measured at temperature measurement device 202, and the temperatures are displayed at user interface and display 196. A control signal is generated by controller 198 that is proportional to the difference between an actual measured temperature, and a desired temperature. The control signal is used by energy circuits 200 to adjust the energy output in an appropriate amount in order to maintain the desired temperature delivered at the respective sensor. A multiplexer can be included to measure current, voltage and temperature, at numerous sensors, and energy can be delivered to the energy delivery device 189 in monopolar or bipolar fashion.

Controller 198 can be a digital or analog controller, or a computer with software. When controller 198 is a computer it can include a CPU coupled through a system bus. On this system can be a keyboard, a disk drive, or other non-volatile memory systems, a display, and other peripherals, as are known in the art. Also coupled to the bus is a program memory and a data memory.

User interface and display 196 includes operator controls and a display. Controller 198 can be coupled to imaging systems, including but not limited to ultrasound, CT scanners, X-ray, MRI, mammographic X-ray and the like. Further, direct visualization and tactile imaging can be utilized.

The output of current sensor 190 and voltage sensor 192 is used by controller 198 to maintain a selected energy level at energy delivery device 189. The amount of energy delivered controls the amount of energy. A profile of energy delivered can be incorporated in controller 198, and a preset amount of energy to be delivered can also be profiled.

Circuitry, software and feedback to controller 198 result in process control, and the maintenance of the selected energy that is independent of changes in voltage or current, and are used to change, (i) the selected energy, (ii) the duty cycle (on-off and wattage), (iii) bipolar or monopolar energy delivery, and (iv) infusion medium delivery, including flow rate and pressure.

These process variables are controlled and varied, while maintaining the desired delivery of energy independent of changes in voltage or current, based on temperatures monitored at sensors 191.

Current sensor 190 and voltage sensor 192 are connected to the input of an analog amplifier 204. Analog amplifier 204 can be a conventional differential amplifier circuit for use with temperature sensors 191. The output of analog amplifier 204 is sequentially connected by an analog multiplexer 206 to the input of A/D converter 208. The output of analog amplifier 204 is a voltage which represents the respective sensed temperatures. Digitized amplifier output voltages are supplied by A/D converter 208 to microprocessor 188. Microprocessor 188 may be a type 68HCII available from Motorola. However, it will be appreciated that any suitable microprocessor or general purpose digital or analog computer can be used to calculate impedance or temperature.

Microprocessor 188 sequentially receives and stores digital representations of impedance and temperature. Each digital value received by microprocessor 188 corresponds to different temperatures and impedances.

Calculated energy and impedance values can be indicated on user interface and display 196. Alternatively, or in addition to the numerical indication of energy or impedance, calculated impedance and energy values can be compared by microprocessor 188 with energy and impedance limits. When the values exceed predetermined energy or impedance values, a warning can be given on user interface and display 196, and additionally, the delivery of RF energy can be reduced, modified or interrupted. A control signal from microprocessor 188 can modify the energy level supplied by energy source 203

Figure 12 illustrates a block diagram of a temperature/impedance feedback system that can be used to control cooling medium flow rate through the catheter into the expandable member. Ablative energy is delivered to energy delivery device 189 by energy source 203, and applied to tissue. A monitor 210 ascertains tissue impedance, based on the energy delivered to tissue, and

compares the measured impedance value to a set value. If the measured impedance exceeds the set value a disabling signal 211 is transmitted to energy source 203, ceasing further delivery of energy to the energy delivery device 189. If measured impedance is within acceptable limits, energy continues to be applied to the tissue. During the application of energy to tissue sensor 191 measures the temperature of tissue and/or energy delivery device 189. A comparator 214 receives a signal representative of the measured temperature and compares this value to a pre-set signal representative of the desired temperature. Comparator 214 sends a signal to a flow regulator 216 representing a need for a higher cooling medium flow rate, if the tissue temperature is too high, or to maintain the flow rate if the temperature has not exceeded the desired temperature.

Figure 13 shows an embodiment of an electrode for ablating tissue. This electrode may be employed, for example, in the device illustrated with regard to Figures 8-9.

As illustrated, the electrode 410 comprises a distal end 409 and a proximal end 408. A tip 411 is disposed near the distal end 409 of the electrode 410. The tip 411 is relatively sharp and is shaped to be able to pierce tissue or other body structures in a region 407 where tissue is to be ablated. In a preferred embodiment, the tip 411 is solid; however, in alternative embodiments, the tip 411 may be hollow, so as to be able to deliver flowable substances by direct flow into the region 407.

For example, such flowable substances may comprise saline, an anesthetic such as lidocaine, an antibiotic or antifungal, a dye or marker, or other bioactive, chemoactive, or radioactive materials.

A membrane 412 is disposed near the tip 411. In a preferred embodiment, the membrane 412 is microporous, so as to be able to deliver flowable substances from the electrode 410 into the region 407 by diffusion. However, in alternative embodiments, the membrane 412 may comprise a

liquid-permeable substance, or may by its shape define a plurality of holes, such as holes which have been drilled or laser-drilled.

In a preferred embodiment, the membrane 412 comprises a relatively solid cylindrical sheath, and preferably comprises porex. However, in alternative embodiments, the membrane 412 may have other shapes. For example, the membrane 412 may comprise a truncated cone.

Alternatively, the electrode 410 may comprise a shape selected to fit within a selected body structure or to avoid a selected body structure, such as a curved shape adapted to avoid facial structures such as the eye or facial bony structures, and the membrane 412 may be shaped to fit within the desired shape for the electrode 410.

Alternatively, the membrane 412 may have an alterable shape, such as being bendable by hand. Alternatively, the membrane 12 may have a dynamic or adaptive shape, such as comprising a balloon or other expandable or collapsible structure.

Alternatively, the membrane 412 may have a shape which is a combination of one or more of the shapes described herein, such as having a first part which is a cylinder and a second part which is a truncated cone.

When using the electrode 410, flowable substances enter a chamber surrounded by the membrane 412 and diffuse through the membrane 412 into the region 407.

In a preferred embodiment, the flowable substances comprise saline, preferably with a concentration of less than about 10%. The presence of saline, or other electrolytes, enables delivery of RF more efficiently and to a more diffused region 407. However, in alternative embodiments, flowable substances in addition to or instead of saline may be delivered to the region 407, either simultaneously with delivery of saline or before or after delivery of saline.

In a preferred embodiment for use ablating soft tissues, the membrane 412 is effective to deliver about 0.1 milliliter of saline in a time period of about 2 to 10 minutes; however, in alternative embodiments it may be advantageous to

provide for greater or lesser flow rates or greater or lesser flow volumes which differ by one to two orders of magnitude, or more.

A conductive element 413 is disposed near the membrane 412 and near the distal end 409 of the electrode 410. In a preferred embodiment, the conductive element 413 comprises a relatively solid cylindrical sheath, having a lumen for flowable substances to flow from a proximal end 408 of the electrode 410 to the membrane 412, and preferably comprises a nickel-titanium alloy. However, in alternative embodiments, the conductive element 413 may have other shapes. For example, the conductive element 413 may comprise truncated cone. Alternatively, the conductive element 413 may be shaped to fit within the desired shape for the electrode 410, as described herein with regard to the membrane 412.

The conductive element 413 preferably has sufficient flex so as to be bendable by hand by an operator. Alternatively, the conductive element 413 may have a dynamic or adaptive shape, such as comprising a balloon or other expandable or collapsible structure.

A tube 414 is coupled at first end to the proximal end 9 of the electrode 410, and is coupled at a second end to a saline source 5 and to an RF energy source 406. The tube 414 comprises a first pathway for saline to be delivered from the saline source 405 to the membrane 412, and a second pathway for a conductor to couple the conductive element 413 to the RF energy source 406.

Figure 14 shows a cross section of an electrode for ablating tissue. The cross section is taken through a line 14--14. A core 421 of the-electrode 410 comprises a lumen into which the flowable substance may flow from the tube 414. In a preferred embodiment, the core 421 comprises an empty tube which allows liquid to flow therethrough on the way to the membrane 412. However, in alternative embodiments, the core 421 may comprise an liquid-absorbing substance, such as a gauze or a porous solid material, for controlling the flow of liquid. The flowable substance may enter the core 421 through the tube 414,

and thereafter flow through the membrane 412, such as shown by the example paths 422.

While the present invention is disclosed by reference to the preferred embodiments and examples detailed above, it is to be understood that these examples are intended in an illustrative rather than limiting sense, as it is contemplated that modifications will readily occur to those skilled in the art, which modifications will be within the spirit of the invention and the scope of the appended claims.

## CLAIMS

1. A method for ablating at least a portion of a nasal concha comprising:

taking a catheter having a distal portion with an expandable member and an energy delivery device coupled to an energy source for delivering ablative energy and positioning the catheter distal portion through a nostril of a patient into a nasal meatus adjacent a surface of a nasal concha;

expanding the expandable member within the nasal meatus so that the expandable member is brought into contact with the surface of the nasal concha; and

delivering sufficient ablative energy from the energy delivery device to the nasal concha to ablate at least a portion of the nasal concha.

2. A method for reducing the size of a nasal concha comprising

delivering ablative energy through a surface of the nasal concha into an interior of the nasal concha without introducing an element into the interior of the nasal concha to ablate a portion of the interior of the nasal concha; and

removing the ablated interior portion of the nasal concha by natural absorption of ablated tissue by the patient's body.

3. A method for reducing the size of a nasal concha without the formation of a external wound comprising:

delivering ablative energy through a surface of the nasal concha into an interior of the nasal concha without introducing an element into the nasal concha to ablate a portion of the interior portion of the nasal concha;

cooling the surface of the nasal concha while delivering ablative energy such that a layer of tissue adjacent the nasal concha surface is not ablated; and

removing the ablated interior portion of nasal concha by natural absorption of ablated tissue by the patient's body.

4. The method according to claims 2 or 3, wherein delivering ablative energy includes taking a catheter having a distal portion with an expandable member and an energy delivery device coupled to an energy source for delivering ablative energy and positioning the catheter distal portion through a nostril of a patient into a nasal meatus adjacent a surface of a nasal concha;

expanding the expandable member within the nasal meatus so that the expandable member is brought into contact with the surface of the nasal concha; and

delivering sufficient ablative energy from the energy delivery device to the nasal concha to ablate at least a portion of the nasal concha.

5. A method for ablating at least a portion of a nasal concha comprising:

taking a catheter having a distal portion with a dimension configured for positioning through a nostril of a patient into a nasal meatus adjacent a nasal concha and an energy delivery device coupled to the catheter distal portion including one or more energy delivering probes;

positioning the catheter distal portion through a nostril of a patient into a nasal meatus adjacent a surface of a nasal concha;

introducing the one or more energy delivering probes into an interior of the nasal concha; and

delivering sufficient ablative energy into the interior of the nasal concha to ablate at least a portion of the nasal concha.

6. A method for ablating at least a portion of a nasal concha comprising:

taking a catheter having a distal portion with a dimension configured for positioning through a nostril of a patient into a nasal meatus adjacent a nasal concha, an expandable member coupled to the catheter distal portion, and an energy delivery device coupled to the catheter distal portion including one or more energy delivering probes;

positioning the catheter distal portion through a nostril of a patient into a nasal meatus adjacent a surface of a nasal concha;

expanding the expandable member within the nasal meatus to immobilize the distal portion within the nasal meatus;

introducing the one or more energy delivering probes into an interior of the nasal concha; and

delivering sufficient ablative energy into the interior of the nasal concha to ablate at least a portion of the nasal concha.

7. The method according to claims 1-6 wherein the portion of the nasal concha ablated is an anterior section of the inferior nasal concha.

8. The method according to claim 7 wherein the portion of the nasal concha ablated is no more than one-third of the inferior nasal concha in the anterior portion of the inferior nasal concha.

9. The method according to claims 1, 2, 4-6 wherein ablating a portion of the nasal concha includes ablating an internal section of the nasal concha without ablating the surface of the nasal concha.

10. The method according to claim 9 wherein ablating an internal section of the nasal concha without ablating the surface of the nasal concha is performed by cooling the surface of the nasal concha during the delivery of energy.

11. The method according to claims 1, 4 or 6 wherein ablating a portion of the nasal concha includes ablating an internal section of the nasal concha without ablating the surface of the nasal concha by cooling the surface of the nasal concha during the delivery of energy by introducing a cool medium into the expandable member during ablation.

12. The method according to claims 1, 3 or 4 wherein ablating a portion of the nasal concha includes ablating an internal section of the nasal concha without penetrating the surface of the nasal concha with an element of the catheter.

13. The method according to claims 1-6 wherein sufficient ablative energy is delivered to heat at least a portion of the nasal concha to a temperature above about 40 °C.

14. The method according to claims 1-14 wherein the ablative energy used is electromagnetic energy.

15. The method according to claim 14 wherein the electromagnetic energy used for ablation is energy selected from the group consisting of RF, microwave, ultrasonic, pulsed laser. and diffuse laser energy.

16. The method according to claim 14 wherein the electromagnetic energy used is RF radiation with a frequency between about 300 megahertz and about 700 megahertz.

17. The method according to claim 14 wherein the electromagnetic energy is RF radiation sufficient to deliver between about 5 and about 30 watts of energy to the portion of the nasal concha being treated.

18. The method according to claims 1, 4 or 6 wherein the expandable member includes a microporous membrane.

19. The method according to claims 1, 4 or 6 wherein the expandable member is expanded by delivering a medium into the expandable member.

20. The method according to claim 19 wherein the delivery of the medium is through a lumen within the catheter into the expandable member.

21. The method according to claim 19 wherein the medium is an electrolytic medium.

22. The method according to claim 21 wherein the electrolytic medium is saline.

23. The method according to claim 22 wherein the saline has a NaCl content of less than about 10% by weight.

24. The method according to claim 22 wherein the electrolytic medium further includes an agent having a bioactive, chemoactive, or radioactive effect.

25. The method according to claim 1-6, further including the step of insulating at least a portion of the nasal meatus from ablative energy during ablation.

26. The method according to claims 1, 4 or 6 further including the step of insulating at least a portion of the nasal meatus from ablative energy during ablation having an insulative covering positioned over a portion of the expandable member to prevent the delivery of energy therethrough.

27. The method according to claims 1-6, wherein the step of delivering ablative energy is performed substantially bloodlessly.

28. The method according to claims 3 or 4, wherein the step of removing the ablated nasal concha tissue is performed substantially bloodlessly.

29. The method according to claims 3 or 4, wherein the step of removing the ablated nasal concha tissue is performed without introducing an element into the nasal concha.

30. The method according to claims 1-3, wherein the nasal concha is reduced in size a sufficient amount to increase the rate of airflow through the nasal meatus at a given pressure by at least 25%.

31. An apparatus for ablating at least a portion of a nasal concha comprising:

a catheter having a distal portion with a dimension configured for positioning the catheter distal portion through a nostril of a patient into a nasal meatus adjacent a surface of a nasal concha;

an expandable member positioned at the catheter distal portion;

an energy delivery device coupleable to an energy source and positioned at the catheter distal portion for delivering ablative energy to the surface of the nasal concha; and

a lumen coupled with the catheter and configured to deliver a medium into the expandable member to expand the expandable member.

32. An apparatus for ablating a selected portion of a nasal concha comprising:

a catheter having a distal portion with a dimension configured for positioning the catheter distal portion through a nostril of a patient into a nasal meatus adjacent a surface of a nasal concha;

an energy delivery device coupleable to an energy source and positioned at the catheter distal portion for delivering ablative energy to the surface of the nasal concha; and

an insulator positioned to cause delivery of ablative energy to a selected portion of a nasal concha while insulating other tissue forming the nasal meatus from the ablative energy.

33. An apparatus for ablating an internal section of a nasal concha comprising:

a catheter having a distal portion with a dimension configured for positioning the catheter distal portion through a nostril of a patient into a nasal meatus adjacent a surface of a nasal concha;

an expandable member positioned at the catheter distal portion;

an energy delivery device coupleable to an energy source and positioned at the catheter distal portion for delivering ablative energy to the surface of the nasal concha;

a lumen positioned within the catheter for delivering a medium into the expandable member to expand the expandable member to adjacent a surface of the nasal concha; and

a medium source for delivering medium of a sufficiently low temperature to cool the surface of the nasal concha during energy delivery so as to prevent ablation of tissue adjacent the surface of the nasal concha.

34. An apparatus for ablating at least a portion of a nasal concha comprising:

a catheter having a distal portion with a dimension configured for positioning the catheter distal portion through a nostril of a patient into a nasal meatus adjacent a surface of a nasal concha; and

a means at the catheter distal portion for delivering sufficient ablative energy to the nasal concha to ablate at least a portion of the nasal concha through heating without penetrating the surface of the nasal concha with an element of the apparatus.

35. An apparatus for ablating an interior portion of a nasal concha without ablating tissue forming a surface of the nasal concha comprising:

a catheter having a distal portion with a dimension configured for positioning the catheter distal portion through a nostril of a patient into a nasal meatus adjacent a surface of a nasal concha; and

a means at the catheter distal portion for delivering sufficient ablative energy to the internal section of the nasal concha to ablate the internal section through heating without ablating the surface of the nasal concha.

36. An apparatus for ablating at least a portion of a nasal concha comprising:

a catheter having a distal portion with a dimension configured for positioning through a nostril of a patient into a nasal meatus adjacent a nasal concha; and

an energy delivery device coupled to the catheter distal portion including one or more energy delivering probes extendable from the catheter distal portion a sufficient distance to be inserted into an interior of the nasal concha to deliver ablative energy therein.

37. An apparatus for ablating at least a portion of a nasal concha comprising:

a catheter having a distal portion with a dimension configured for positioning through a nostril of a patient into a nasal meatus adjacent a nasal concha;

an energy delivery device coupled to the catheter distal portion including one or more energy delivering probes extendable from the catheter distal portion a sufficient distance to be inserted into an interior of the nasal concha to deliver ablative energy therein; and

an energy source coupled to the energy delivery device for delivering energy to the probes.

38. An apparatus for ablating at least a portion of a nasal concha comprising:

a catheter having a distal portion with a dimension configured for positioning through a nostril of a patient into a nasal meatus adjacent a nasal concha, the distal portion including an expandable member, expansion of the expandable member within the nasal meatus immobilizing the distal portion within the nasal meatus; and

an energy delivery device coupled to the catheter distal portion including one or more energy delivering probes extendable from the catheter distal portion a sufficient distance to be inserted into an interior of the nasal concha to deliver ablative energy therein.

39. An apparatus for ablating an interior portion of a nasal concha comprising:

a catheter having a distal portion with a dimension configured for positioning through a nostril of a patient into a nasal meatus adjacent a surface of a nasal concha;

an energy delivery device coupled to the catheter distal portion including one or more energy delivering probes extendable from the catheter distal portion a sufficient distance to be inserted into an interior of the nasal concha to deliver ablative energy therein; and

an expandable member coupled to the distal portion having a cooling surface, expansion of the expandable member within the nasal meatus placing the cooling surface into contact with a surface of the nasal concha to cool the nasal concha surface.

40. The apparatus according to claims 31, 33, 38 or 39 wherein the expandable member when expanded conforms to the surface of the nasal concha.

41. The apparatus according to claims 31 or 33 wherein the energy delivery device is positioned within the expandable member.

42. The apparatus according to claims 31 or 33 wherein the energy delivery device is positioned on a surface of the expandable member.

43. The apparatus according to claims 31 or 33 wherein the energy delivery device includes one or more ring electrodes.

44. The apparatus according to claim 43 wherein the one or more ring electrodes are disposed in parallel with their axes aligned with a long axis of the catheter.

45. The apparatus according to claims 31, 33, 38 or 39 wherein the expandable member is permeable to an electrolytic solution.

46. The apparatus according to claims 31, 33, 38 or 39 wherein the expandable member includes a sheath substantially surrounding the lumen having apertures through which the medium can pass from the lumen into the expandable member.

47. The apparatus according to claims 31, 33, 38 or 39 wherein the apparatus further includes an insulator for preventing the delivery of ablative energy through at least a portion of the expandable member.

48. The apparatus according to claim 47 wherein the insulator is an insulative covering positioned over a portion of a surface of the expandable member.

49. The apparatus according to claims 31, 33, 38 and 39 wherein the expandable member is an expandable porous membrane.

50. The apparatus according to claims 31, 32, 33, or 36-39 wherein the energy delivery device is for delivering electromagnetic energy.

51. The apparatus according to claim 50 wherein the energy delivery device is for delivering energy selected from the group consisting of RF, microwave, ultrasonic, pulsed laser and diffuses laser energy.

52. The apparatus according to claim 50 wherein the energy source provides electromagnetic energy and a signal generator coupled to the energy source for generating pulses of electromagnetic energy having a frequency between about 300 and 700 megahertz.

53. The apparatus according to claim 50, wherein the energy source produces RF energy and the apparatus further includes a processor coupled to the signal generator for generating pulses of RF energy which provide between about 5 and about 30 watts of RF energy.

54. The apparatus according to claim 50, wherein the expandable member further includes at least one sensor coupled to the processor.

55. The apparatus according to claim 54, wherein the sensor measures a property selected from the group consisting of an amount of energy delivered by the energy delivery device, an amount of heat generated at a location; an amount of impedance generated, and a temperature at a location.

56. The apparatus according to claim 55, wherein the energy delivered to the energy delivery device is controlled by the processor in response to a

measured property selected from the group consisting of an amount of energy delivered by the energy delivery device, an amount of heat generated at a location; an amount of impedance generated, and a temperature at a location.

57. The apparatus according to claim 56, wherein the apparatus includes a sensor for measuring the measured property.

58. The apparatus according to claim 34 or 35 wherein the apparatus further includes an insulating means for preventing the delivery of ablative energy to a selected tissue section forming a portion of the nasal meatus.

59. The apparatus according to claims 34 or 35 wherein the apparatus further includes an insulating means for preventing the delivery of ablative energy to a selected portion of the nasal concha.

60. The apparatus according to claims 34 or 35 wherein the energy delivery means delivers electromagnetic energy.

61. The apparatus according to claims 34 or 35 wherein the energy delivery means delivers energy selected from the group consisting of RF, microwave, ultrasound, pulsed laser, and diffused laser energy.

62. The apparatus according to claims 34 or 35 wherein the energy delivery means delivers RF radiation with a frequency between about 300 megahertz and about 700 megahertz.

63. The apparatus according to claims 34 or 35 wherein the energy delivery means delivers sufficient RF radiation to deliver between about 5 and about 30 watts of energy to the portion of the nasal concha being ablated.

64. The apparatus according to claims 34 or 35 wherein the energy delivery means delivers ablative energy through the surface of the nasal concha into an interior section of the nasal concha.

65. The apparatus according to claims 34 or 35 wherein the energy delivery means delivers ablative energy through the surface of the nasal concha into an interior section of the nasal concha substantially bloodlessly.

66. The apparatus according to claims 34 or 35 wherein the energy delivery means delivers ablative energy through the surface of the nasal concha into an interior section of the nasal concha without the formation of an external wound on the surface of the nasal concha.

67. The apparatus according to claims 34 or 35 wherein the energy delivery means delivers ablative energy to the internal section of the nasal concha without penetrating the surface of the nasal concha with an element of the apparatus.

68. The apparatus according to claims 34 or 35 wherein the energy delivery means delivers ablative energy to the internal section of the nasal concha without the formation of a wound on the surface of the nasal concha.

69. The apparatus according to claims 34 or 35 wherein the apparatus further includes a cooling means for cooling the surface of the nasal concha during the delivery of ablative energy.

70. The apparatus according to claim 69 wherein the cooling means is adapted to receive a cool medium from a medium source to cool the surface of the nasal concha.

71. The apparatus according to claims 34 or 35 wherein the apparatus includes an expandable member which conforms to the surface of the nasal concha when expanded.

72. The apparatus according to claims 34 or 35 wherein the apparatus further includes an insulating means for preventing the delivery of ablative energy to a selected tissue section forming a portion of the nasal meatus.

73 The apparatus according to claims 31-39, wherein the catheter distal portion further includes at least one sensor for measuring a property selected from the group consisting of an amount of energy delivered by the energy delivery device, an amount of heat generated at a location, an amount of impedance generated, and a temperature at a location.

74. The apparatus according to claim 73, wherein the energy delivered to the energy delivery device is controlled by a processor in response to a property measured by the sensor.

75. The apparatus according to claims 36-39 wherein the one or more energy delivering probes extend a fixed distance from the catheter distal portion.

76. The apparatus according to claims 36-39 wherein the one or more energy delivering probes are retractable into the catheter distal portion and extendable from the catheter distal portion.

77. The apparatus according to claims 36-39 wherein the energy delivery device includes at least two energy delivering probes.

78. The apparatus according to claims 36-39 wherein the one or more energy delivering probes deliver energy selected from the group consisting of RF, microwave, ultrasonic, pulsed laser and diffuse laser energy.

79. The apparatus according to claims 36-39 wherein the one or more energy delivering probes are needle electrodes for delivering RF energy.

80. The apparatus according to claims 36-39 wherein the one or more energy delivering probes include an optical fiber for delivering laser energy.

81. The apparatus according to claims 36-39 wherein the one or more energy delivering probes are antenna for delivering microwave energy.

82. The apparatus according to claims 36-39 wherein the one or more energy delivering probes include transducers for delivering ultrasonic energy.

83. The apparatus according to claims 36-39 wherein the apparatus further includes an insulator positioned adjacent at least a portion of the one or more energy delivering probes to prevent the delivery of energy therethrough.

84. The apparatus according to claim 83 wherein the insulator is movable relative to the one or more energy delivering probes.

85. The apparatus according to claim 39 wherein the cooling surface provides sufficiently cooling to prevent the ablation of the nasal concha surface.

86. The apparatus according to claim 39, further including

a lumen positioned within the catheter for delivering a medium into the expandable member to expand the expandable member adjacent the surface of the nasal concha; and

a medium source for delivering medium of a sufficiently low temperature to cool the surface of the nasal concha.

87. The apparatus according to claim 39 wherein expansion of the expandable member also serves to immobilize the catheter distal end within the nasal meatus.

88. The apparatus according to claim 39 wherein the expandable member includes a sheath substantially surrounding the lumen having apertures through which the medium can pass from the lumen into the expandable member.

89. The apparatus according to claim 39 wherein the expandable member conforms to the surface of the nasal concha when expanded.

90. The apparatus according to claim 39 wherein the expandable member conforms to a contour of the nasal meatus when expanded.

91. The apparatus according to claim 39 wherein the one or more energy delivering probes are retractable into the catheter distal portion and extendable from the catheter distal portion.

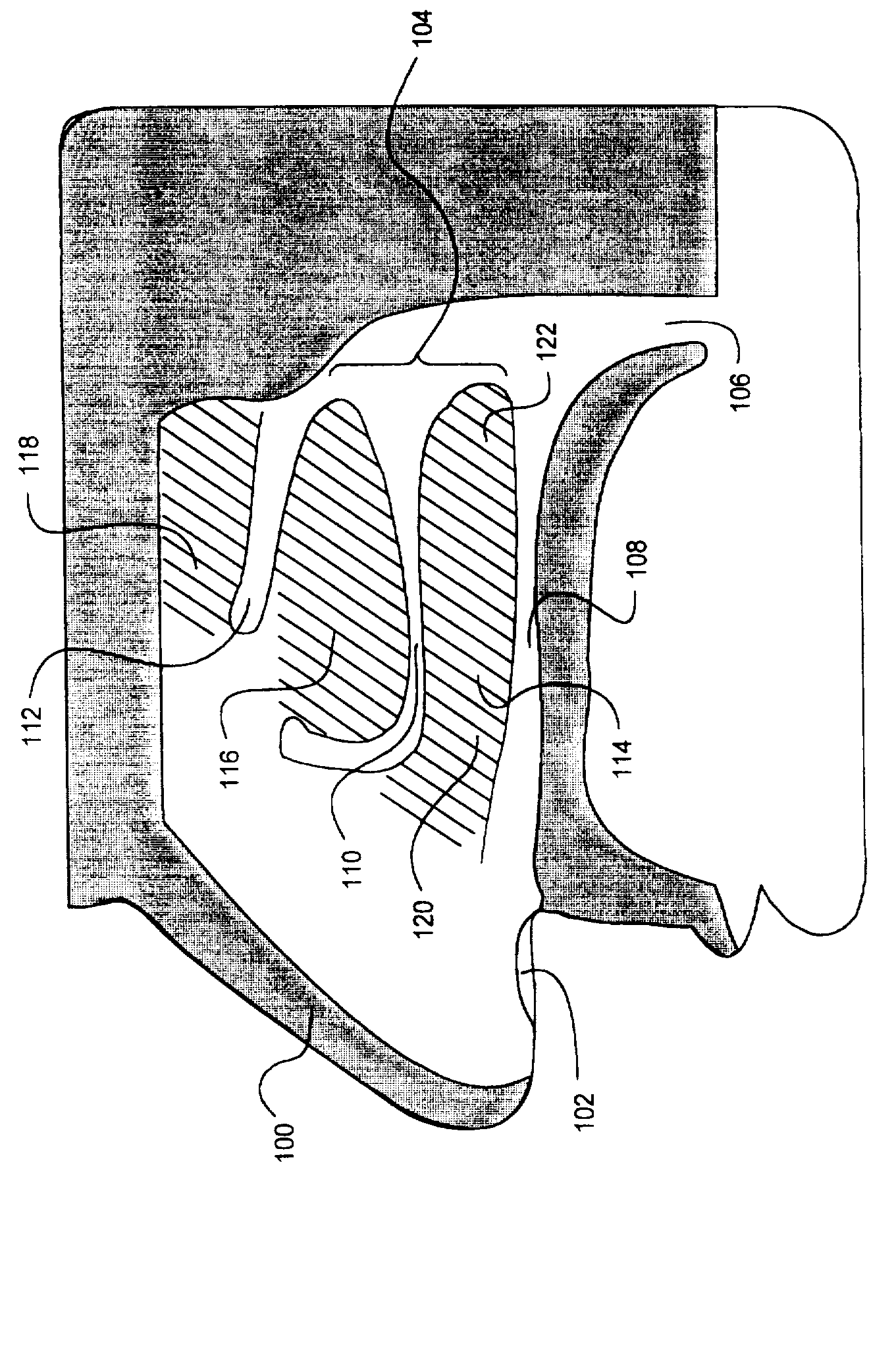



FIG. 1

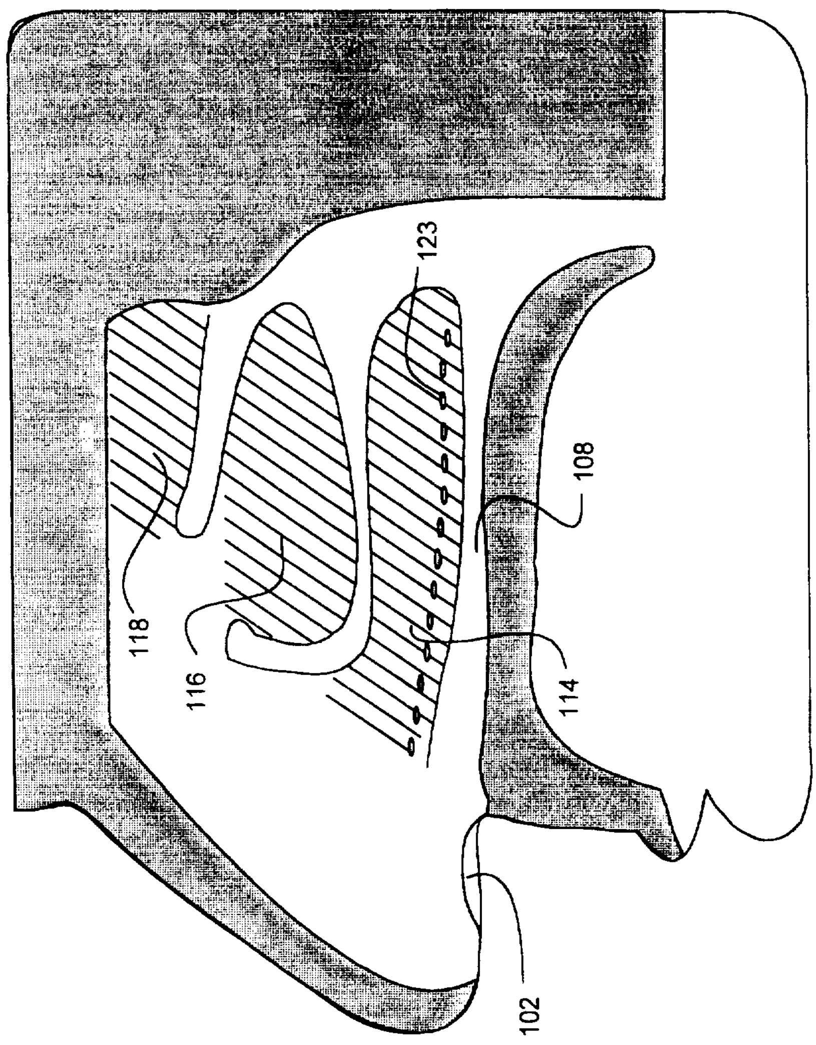



FIG. 2

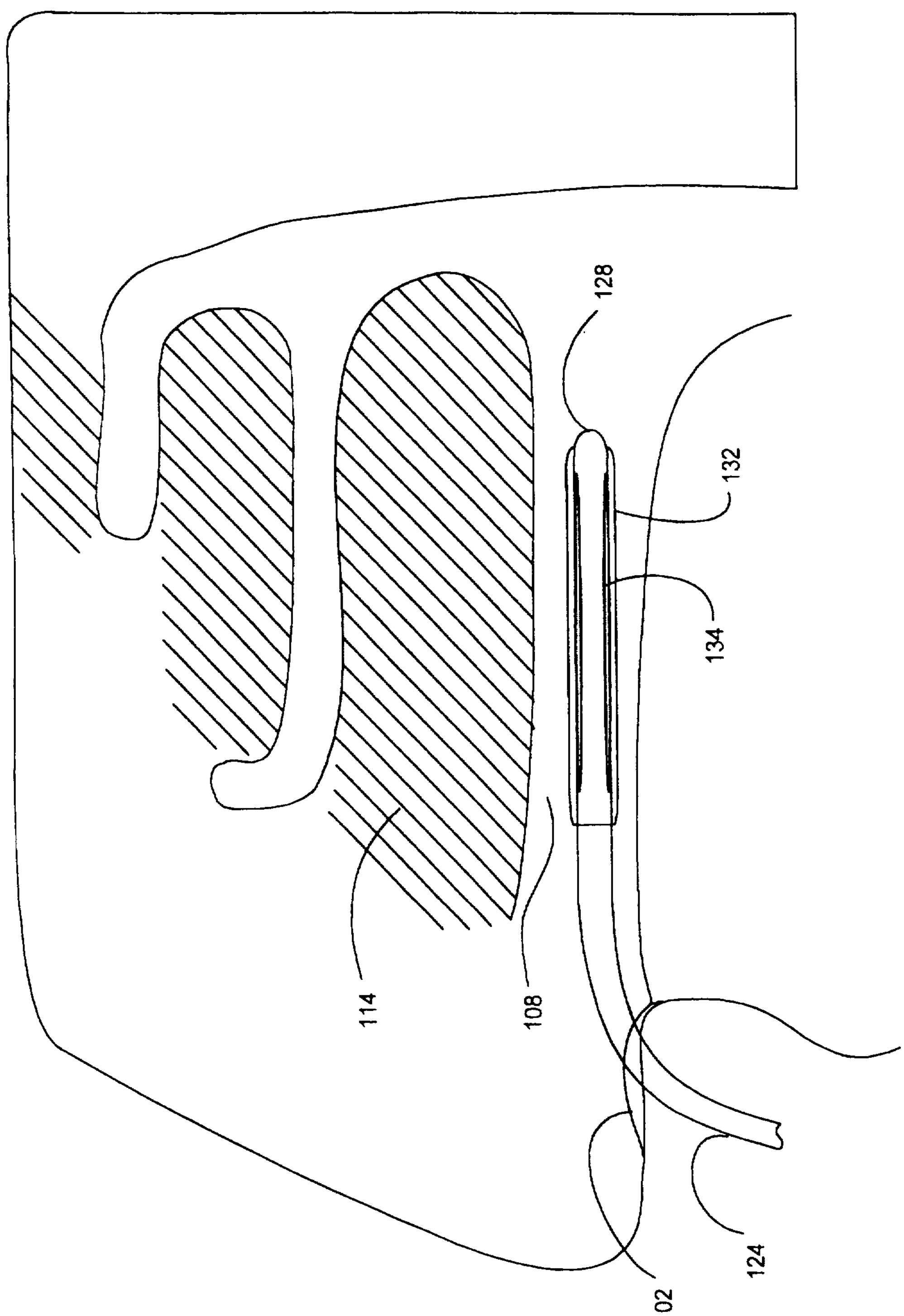



FIG. 3A

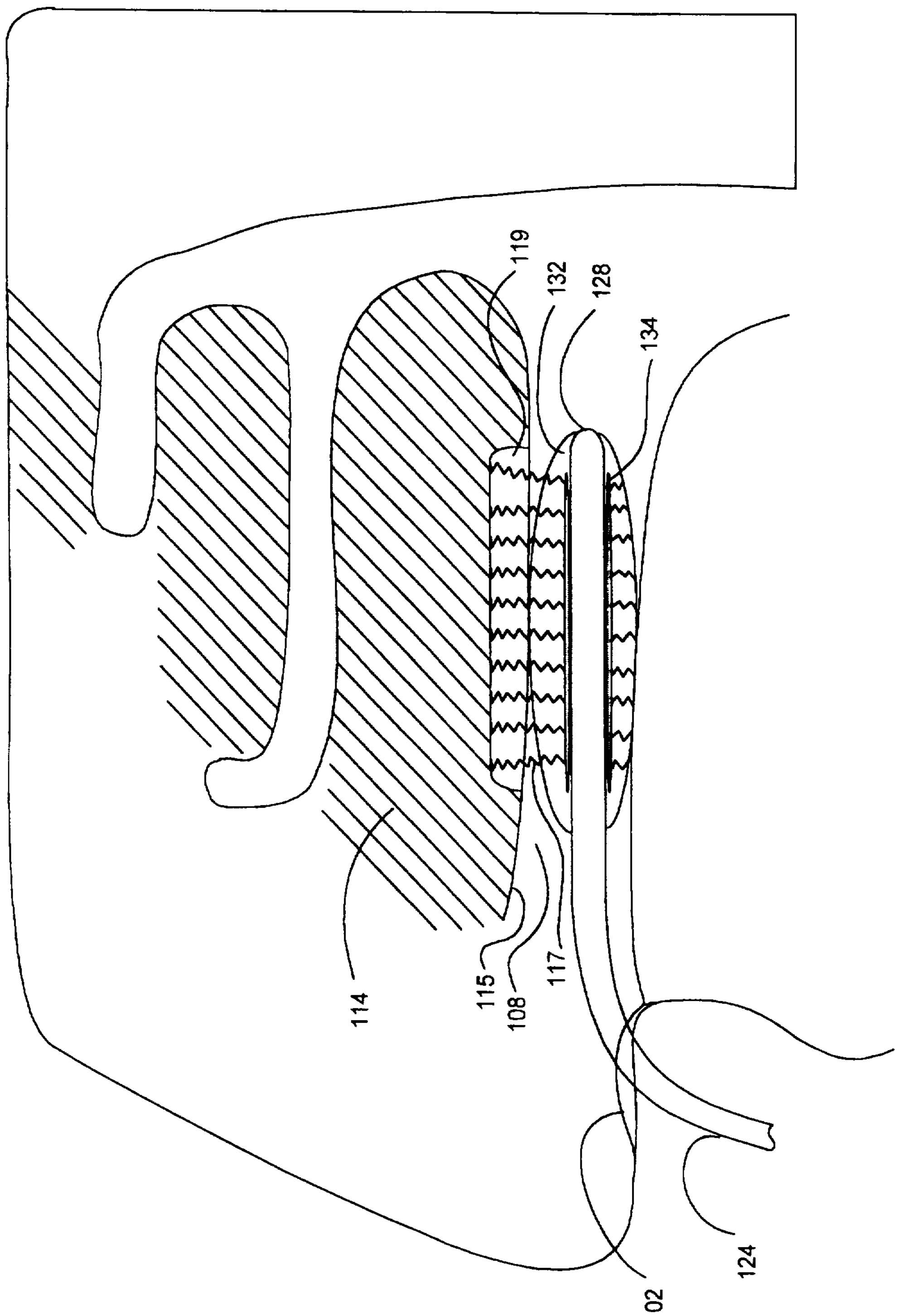



FIG. 3B

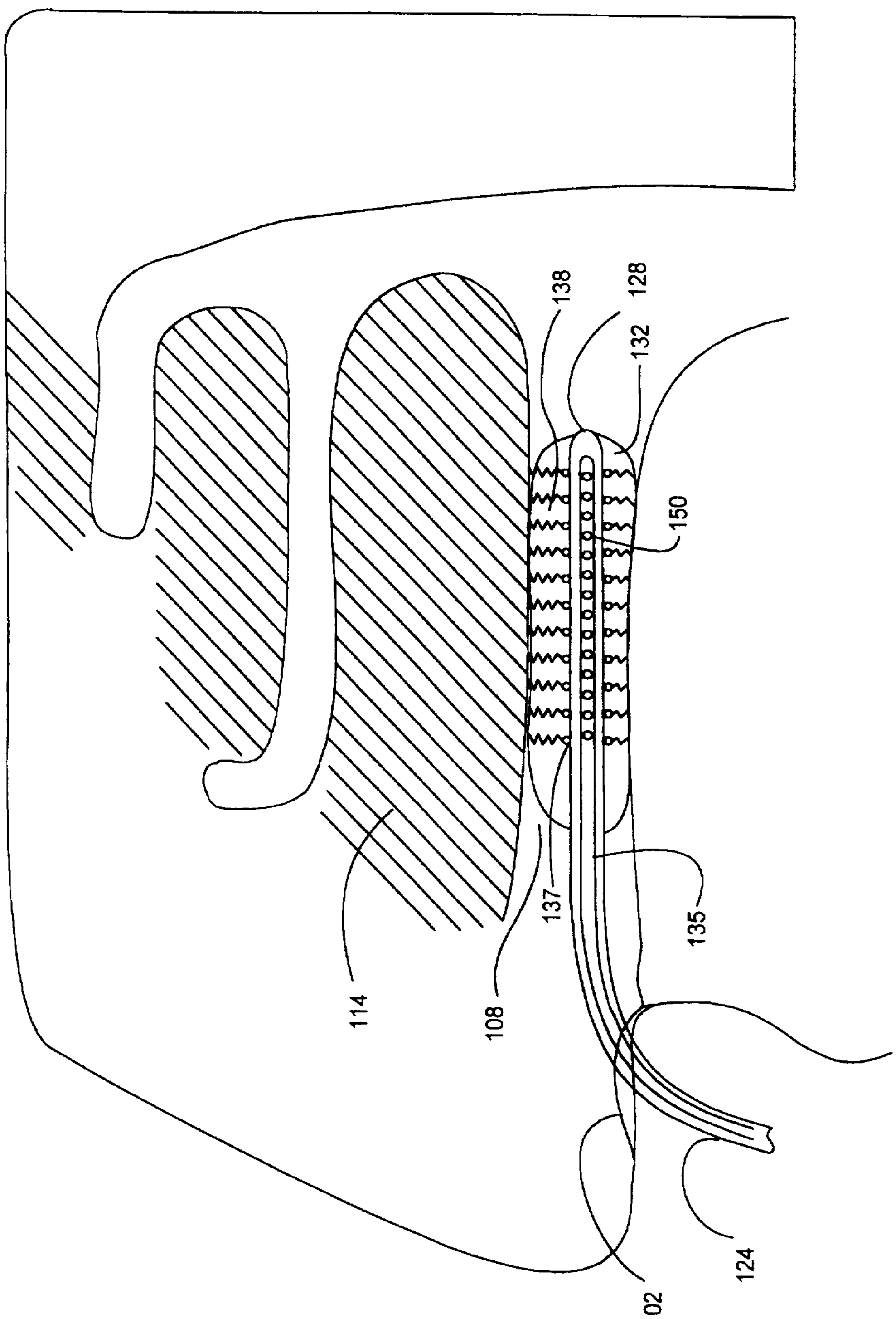



FIG. 3C

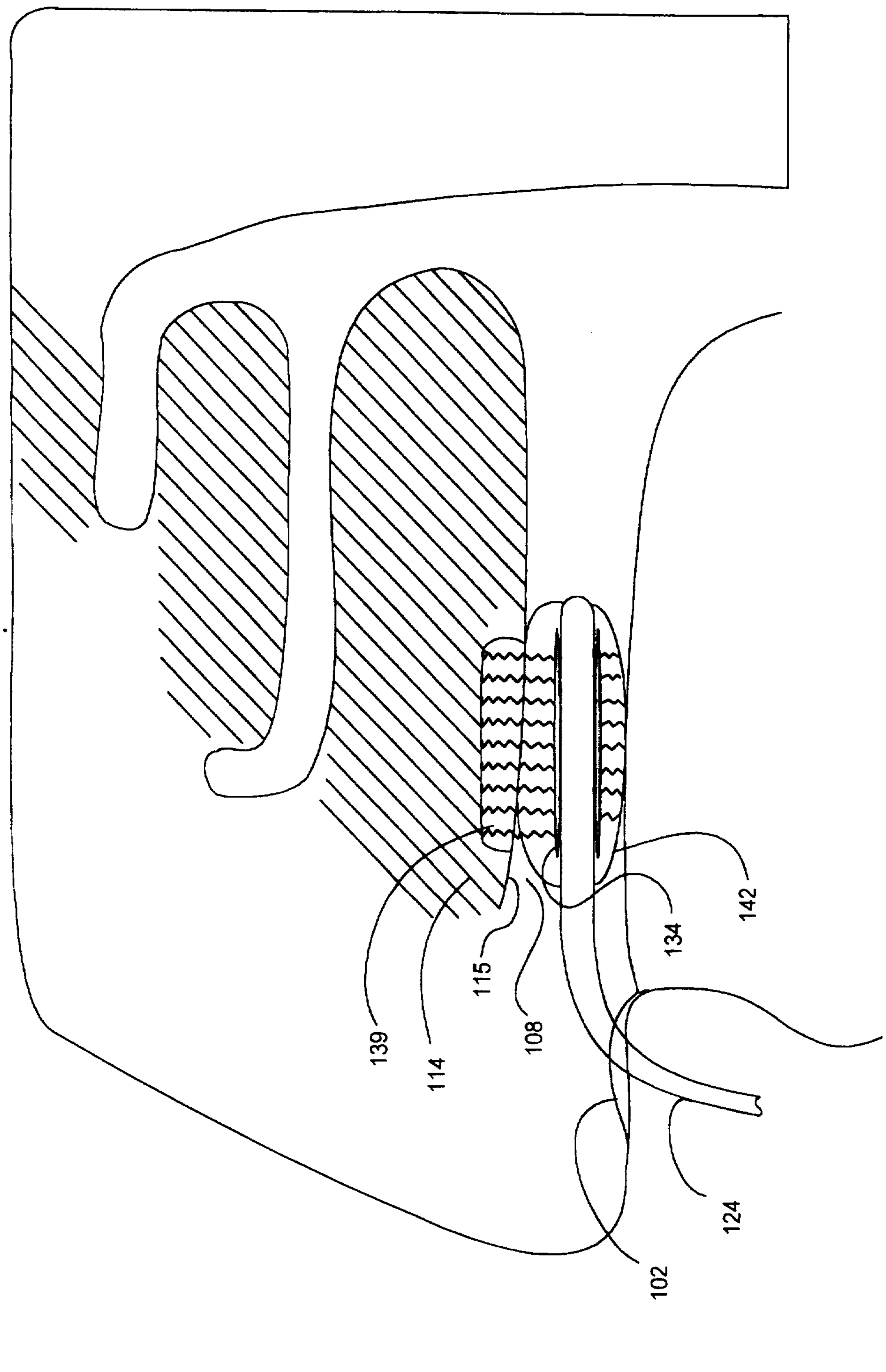



FIG. 3D

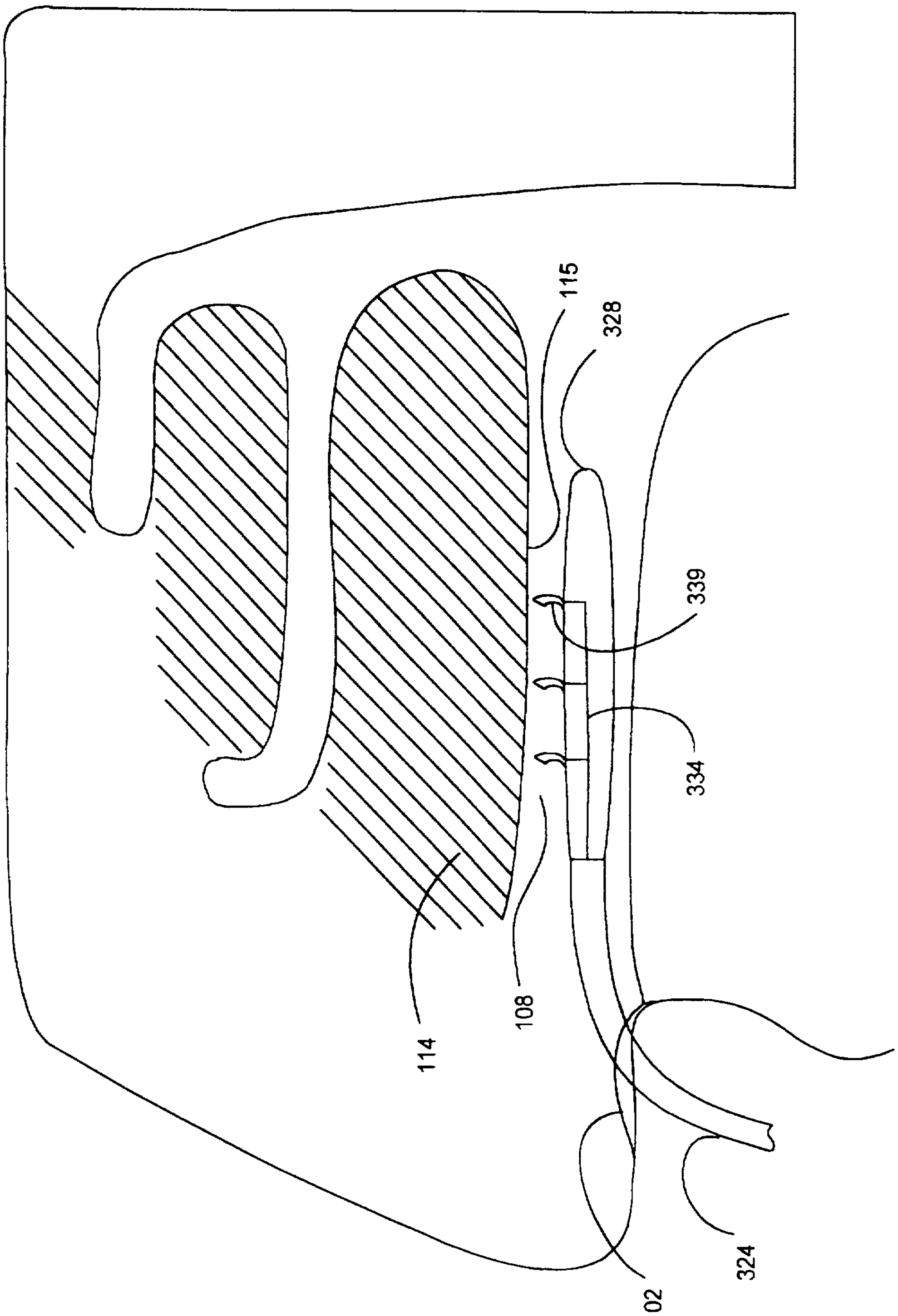



FIG. 3E

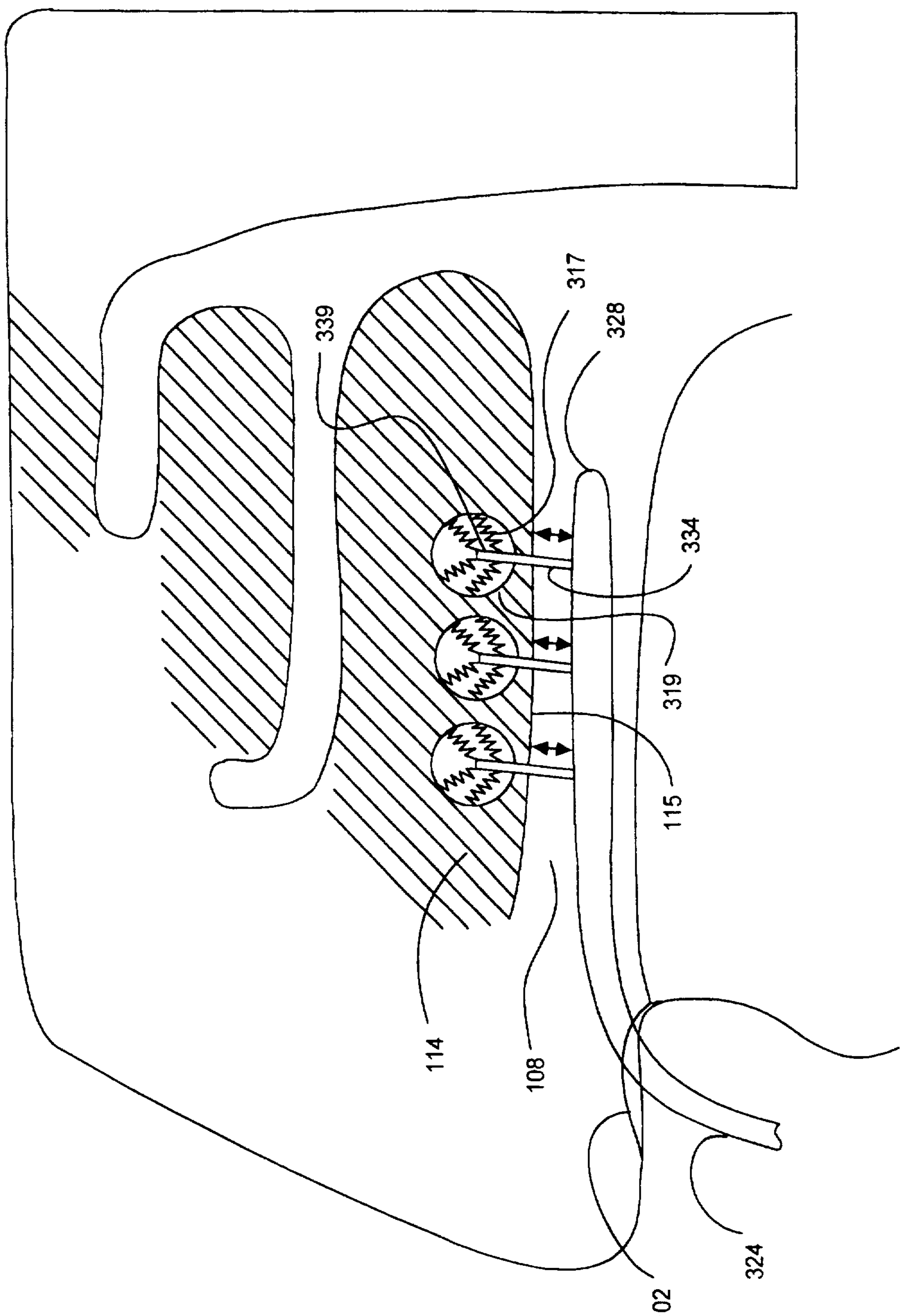
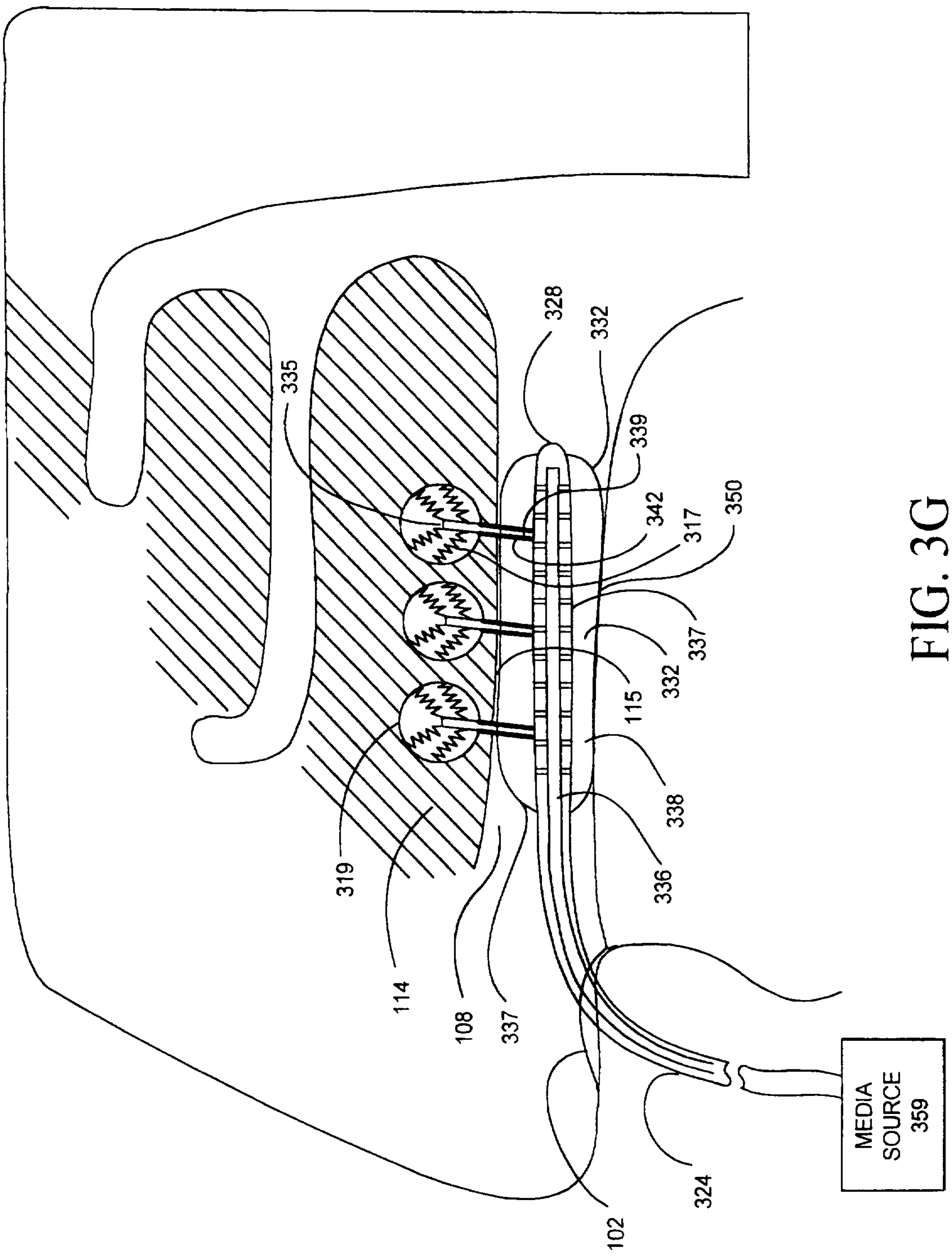



FIG. 3F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MEDIA
SOURCE
359

FIG. 3G

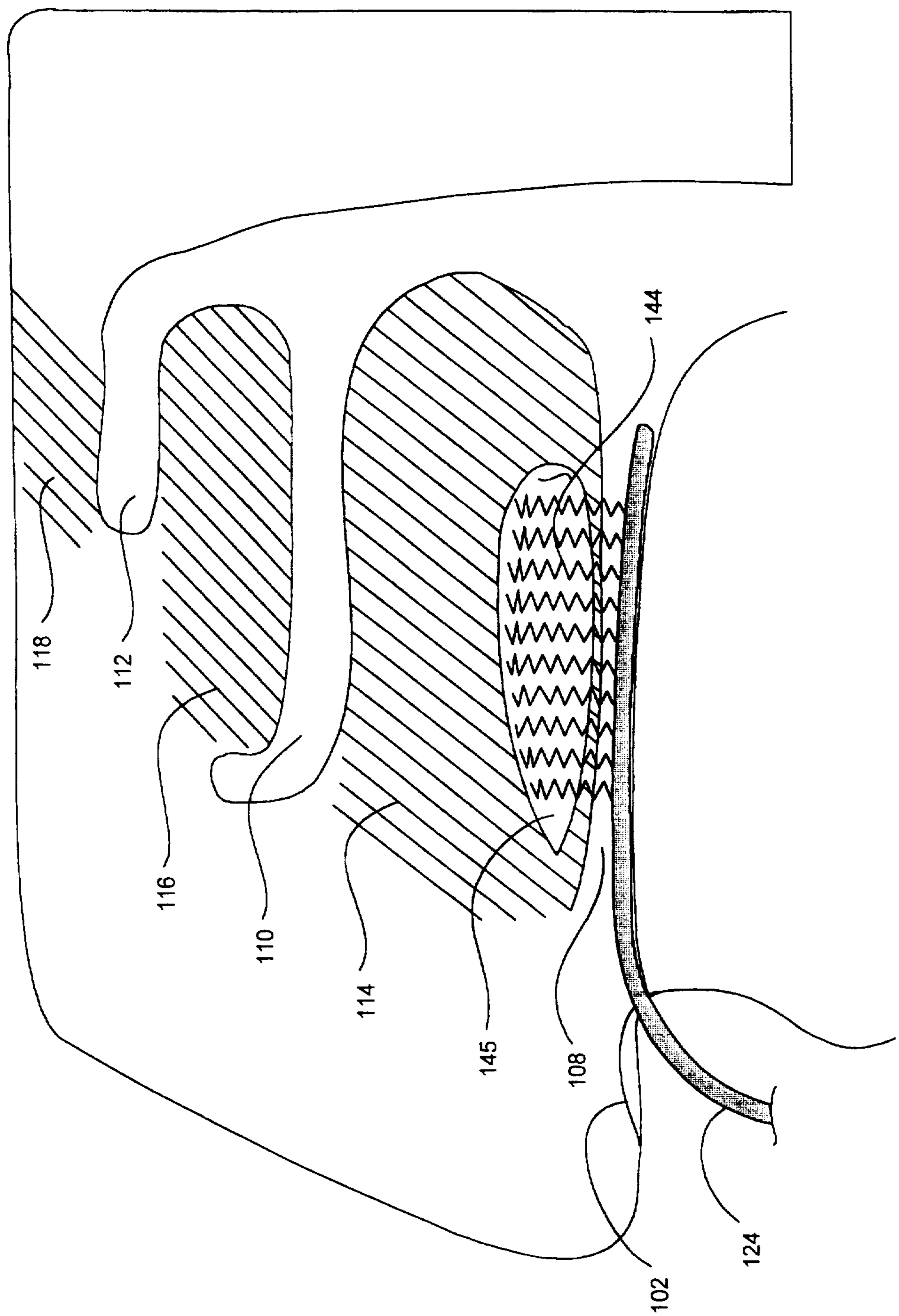



FIG. 4A

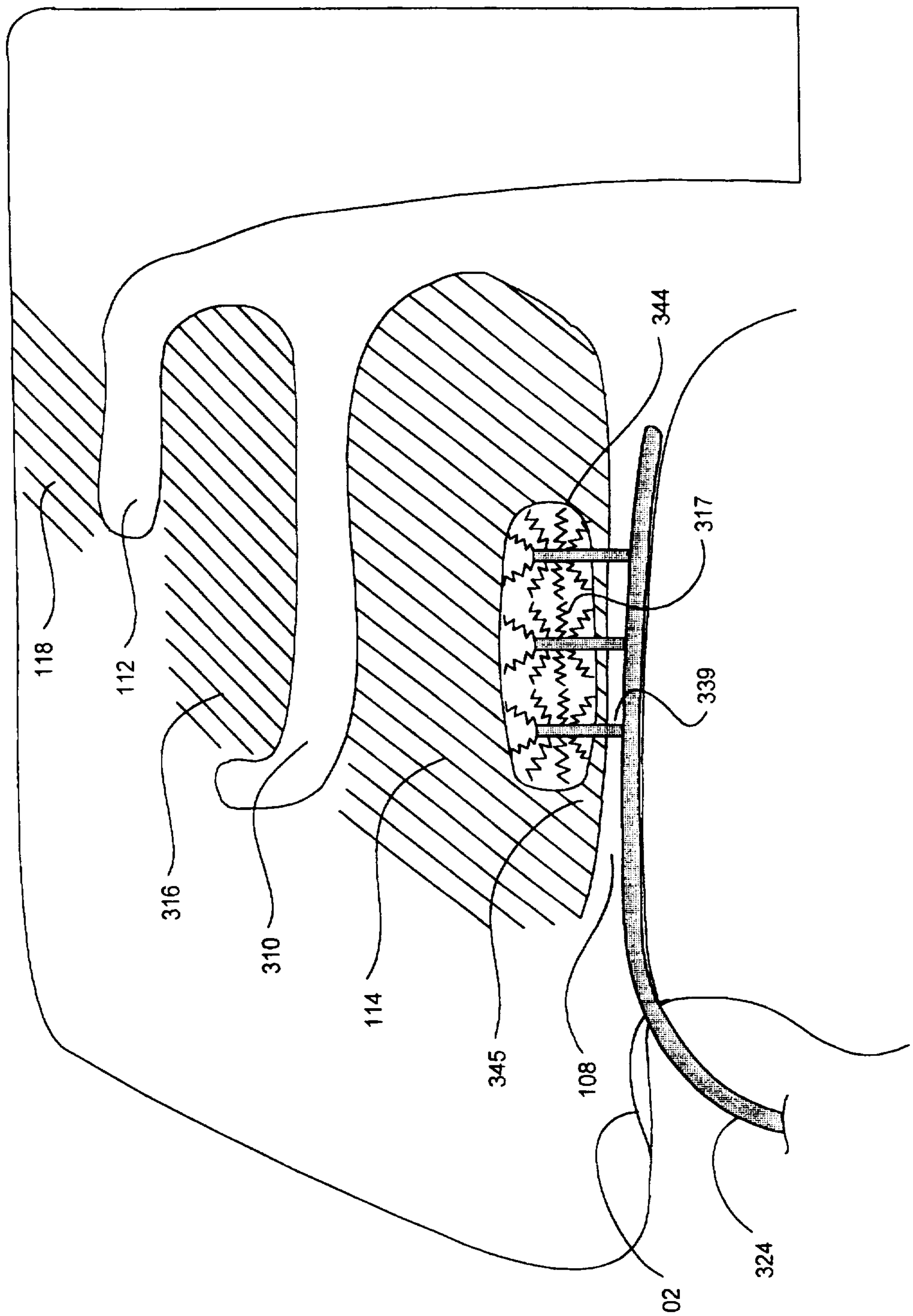



FIG. 4B

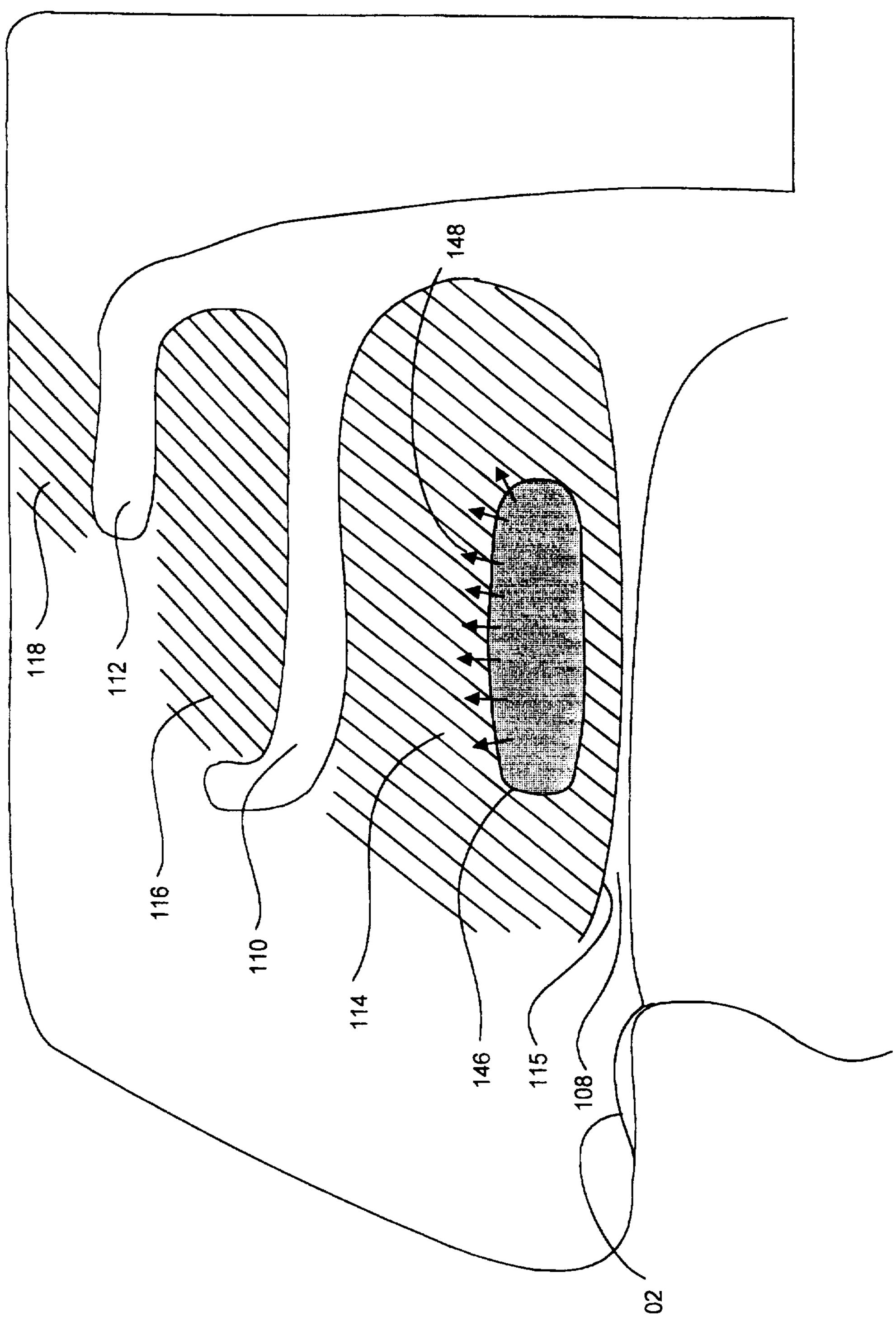



FIG. 4C

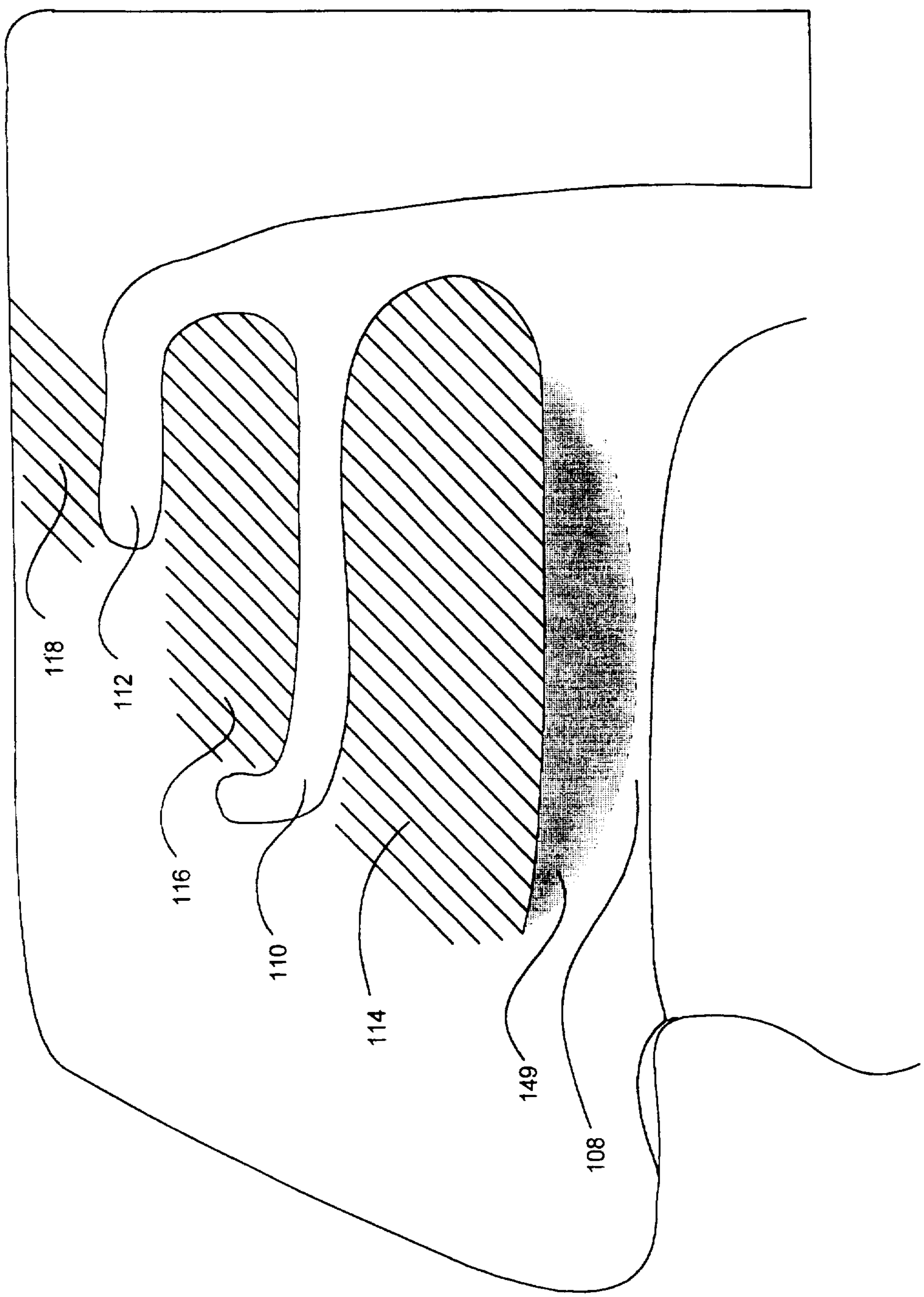
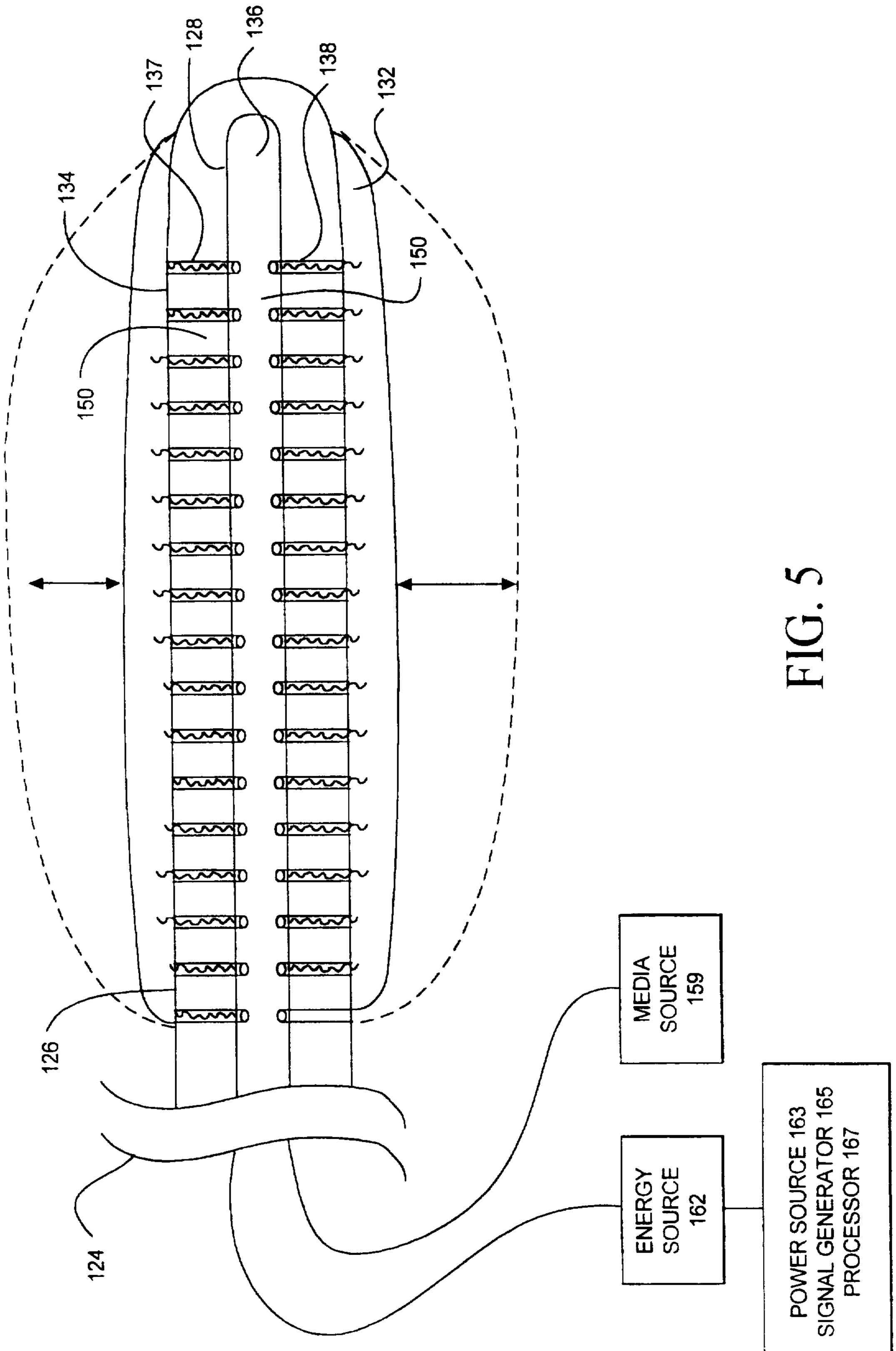



FIG. 4D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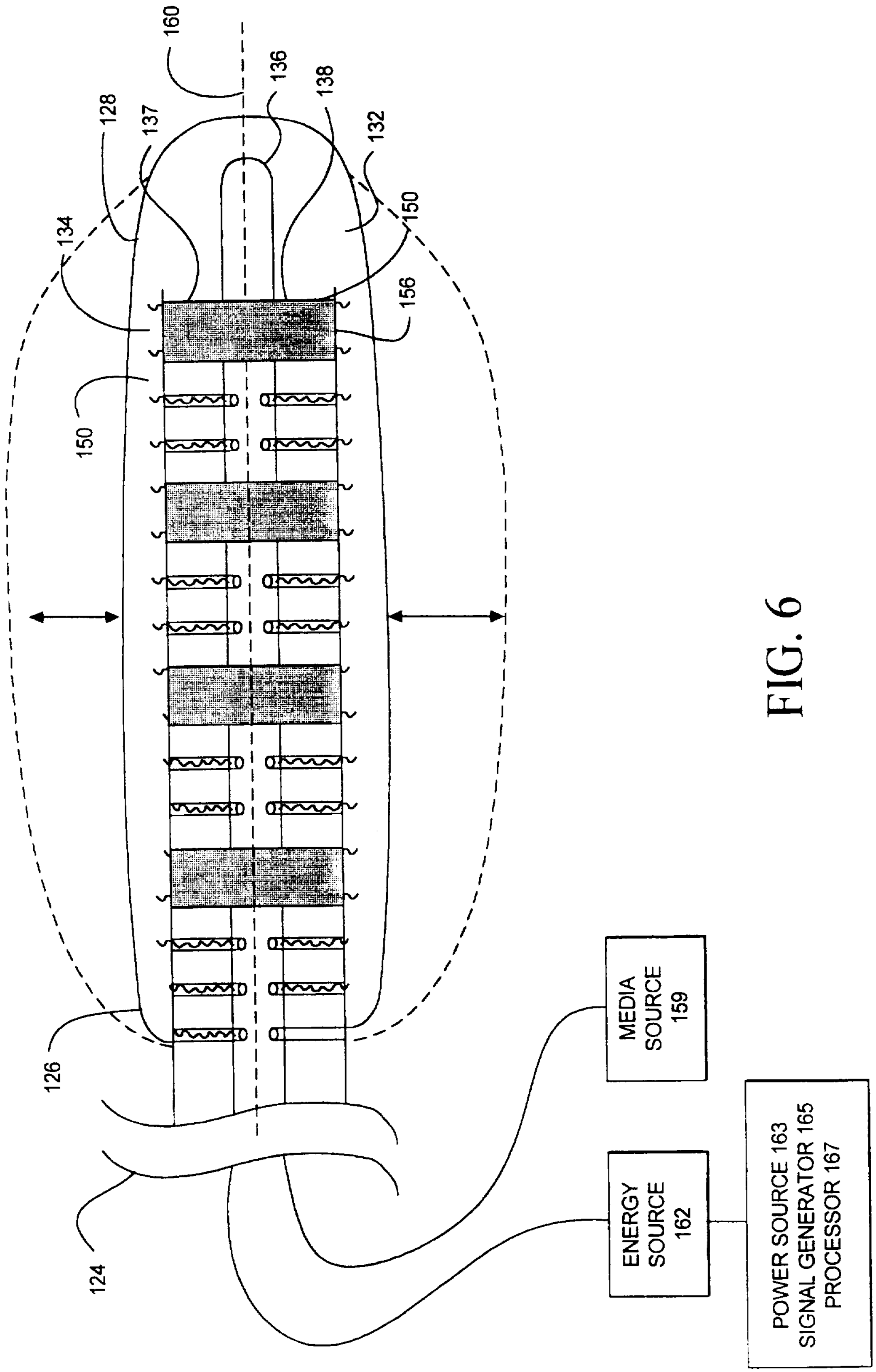
ENERGY SOURCE 162
POWER SOURCE 163
SIGNAL GENERATOR 165
PROCESSOR 167

FIG. 5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MEDIA SOURCE 159
ENERGY SOURCE 162
POWER SOURCE 163
SIGNAL GENERATOR 165
PROCESSOR 167

FIG. 6

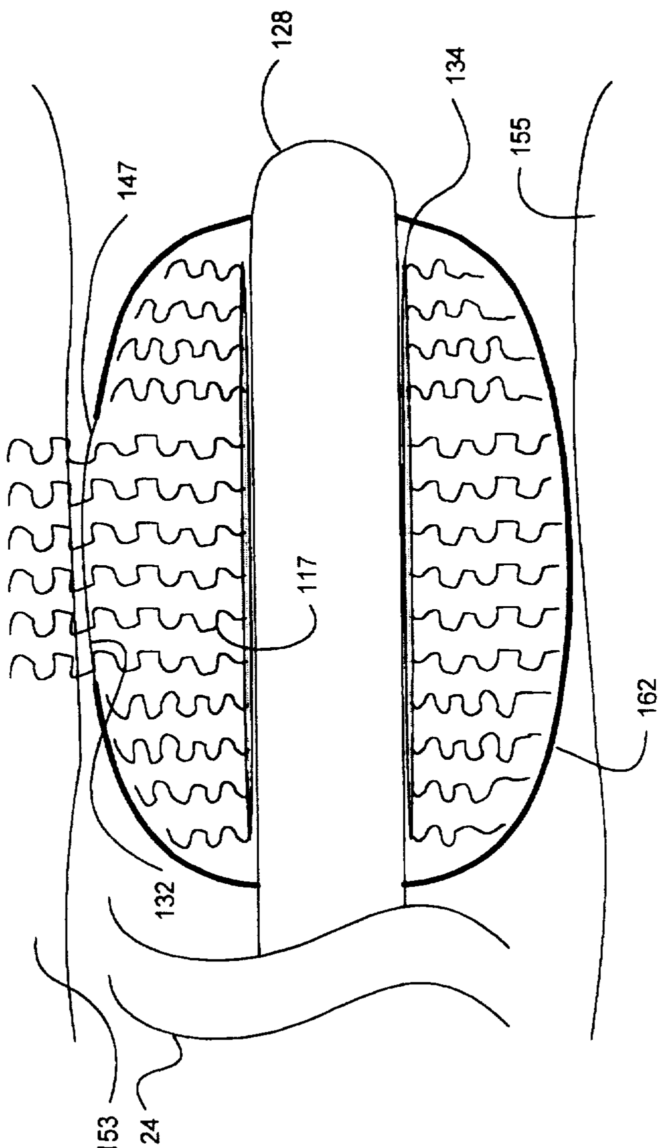
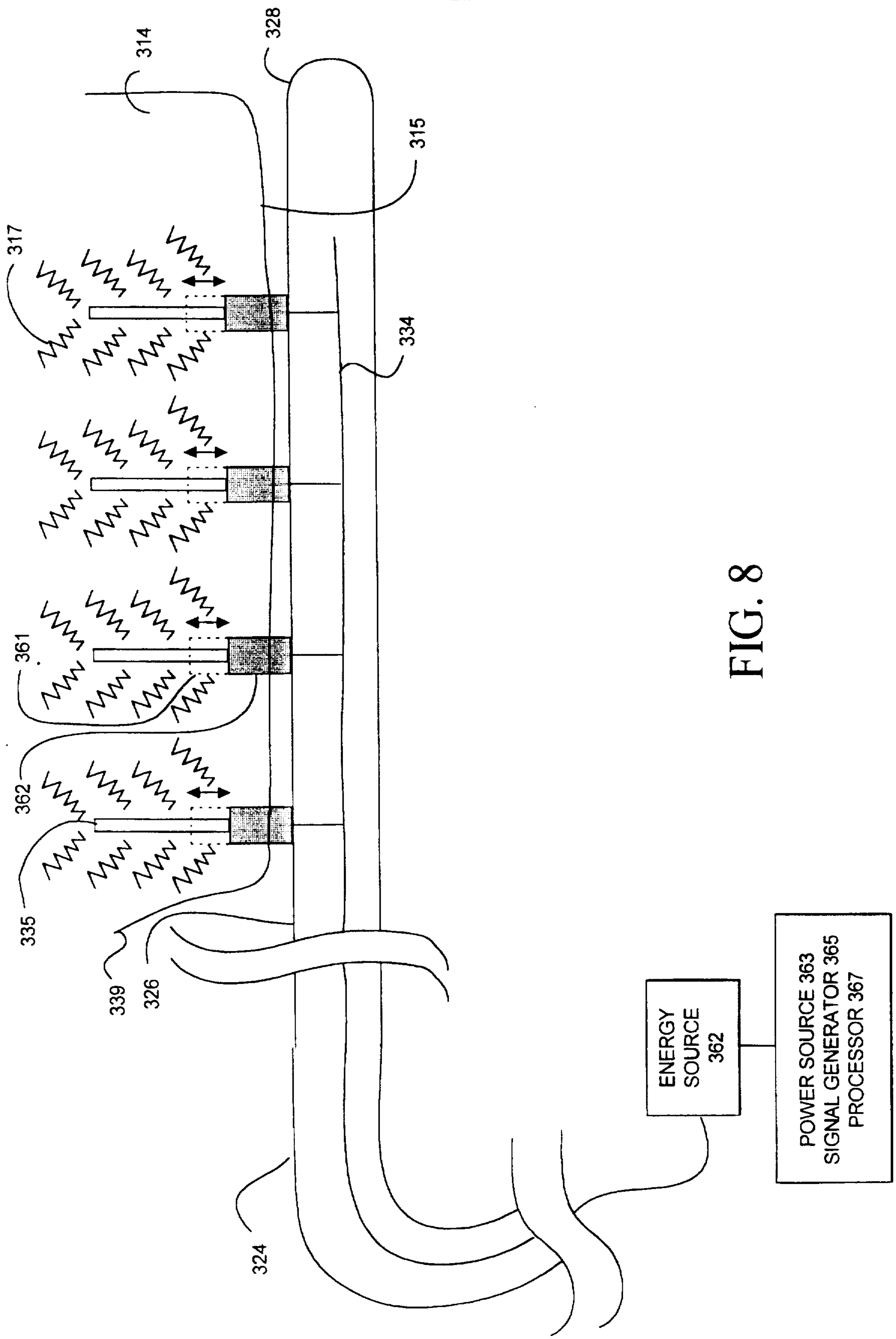



FIG. 7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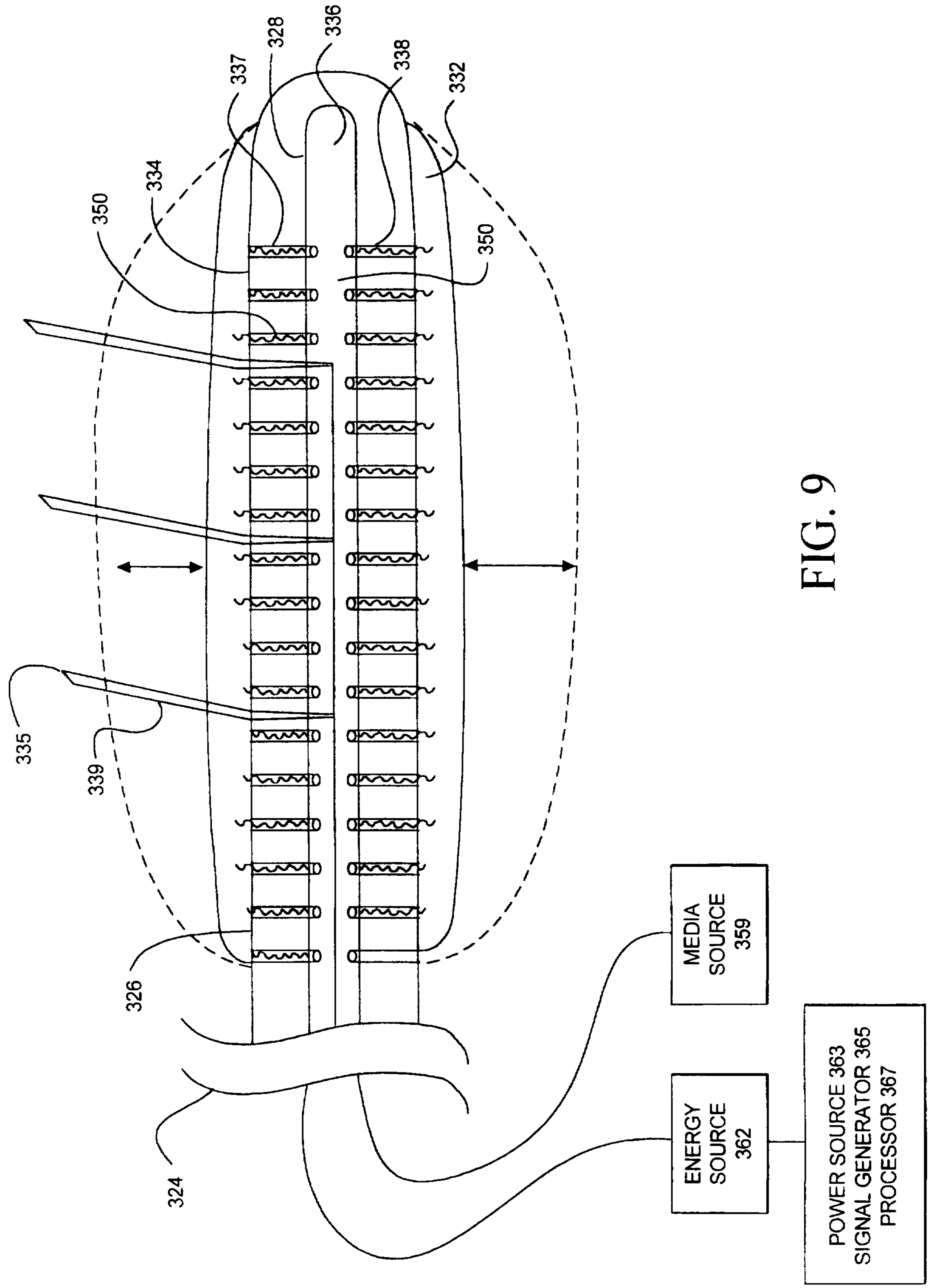
POWER SOURCE 363
SIGNAL GENERATOR 365
PROCESSOR 367

FIG. 8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POWER SOURCE 363
SIGNAL GENERATOR 365
PROCESSOR 367

FIG. 9

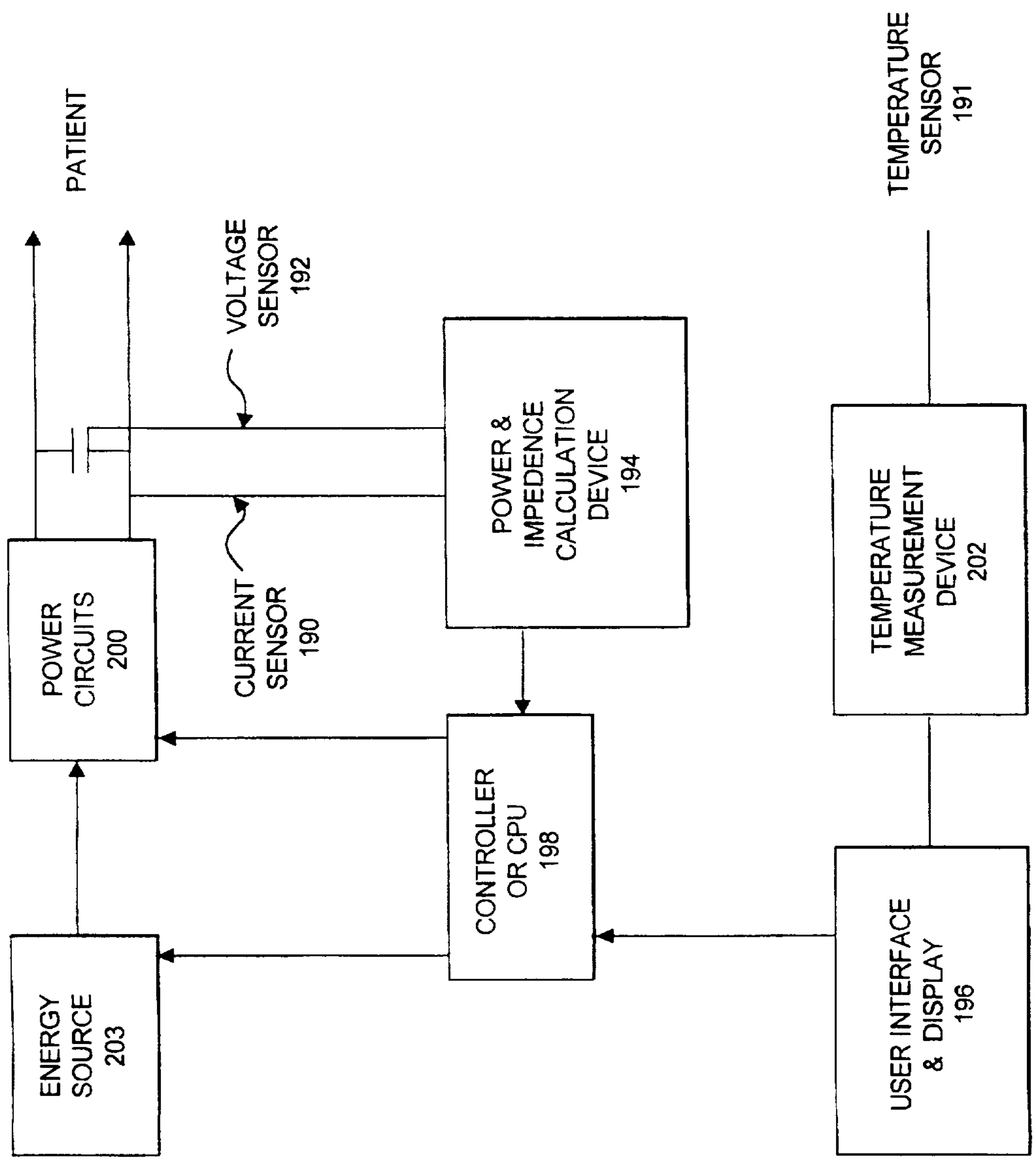
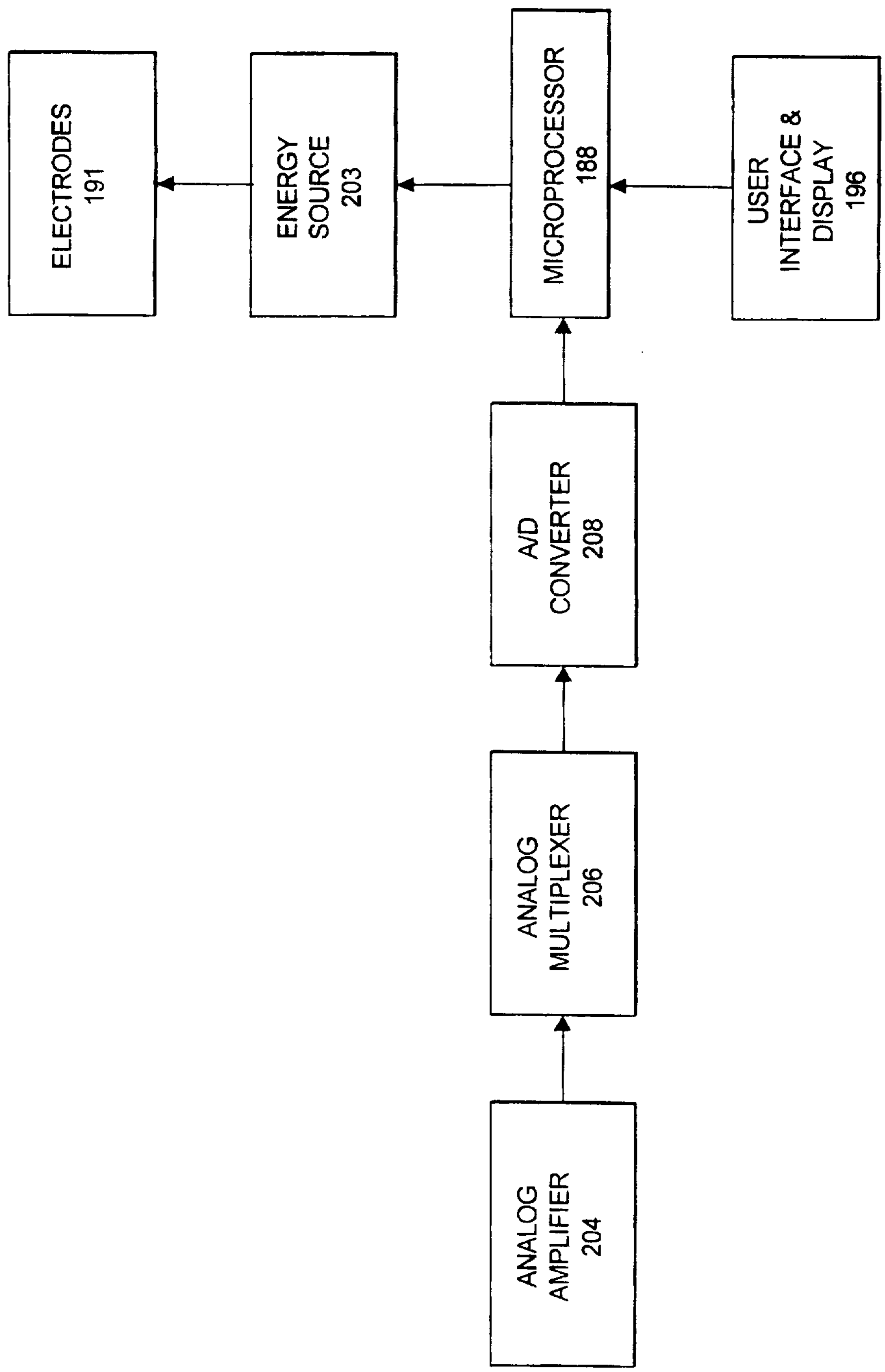

PATIENT
VOLTAGE SENSOR 192
TEMPERATURE SENSOR 191
POWER & IMPEDENCE CALCULATION DEVICE 194
CURRENT SENSOR 190
POWER CIRCUITS 200
TEMPERATURE MEASUREMENT DEVICE 202
CONTROLLER OR CPU 198
ENERGY SOURCE 203
USER INTERFACE & DISPLAY 196

FIG. 10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191
ENERGY
SOURCE
203
MICROPROCESSOR
188
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INTERFACE &
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A/D
CONVERTER
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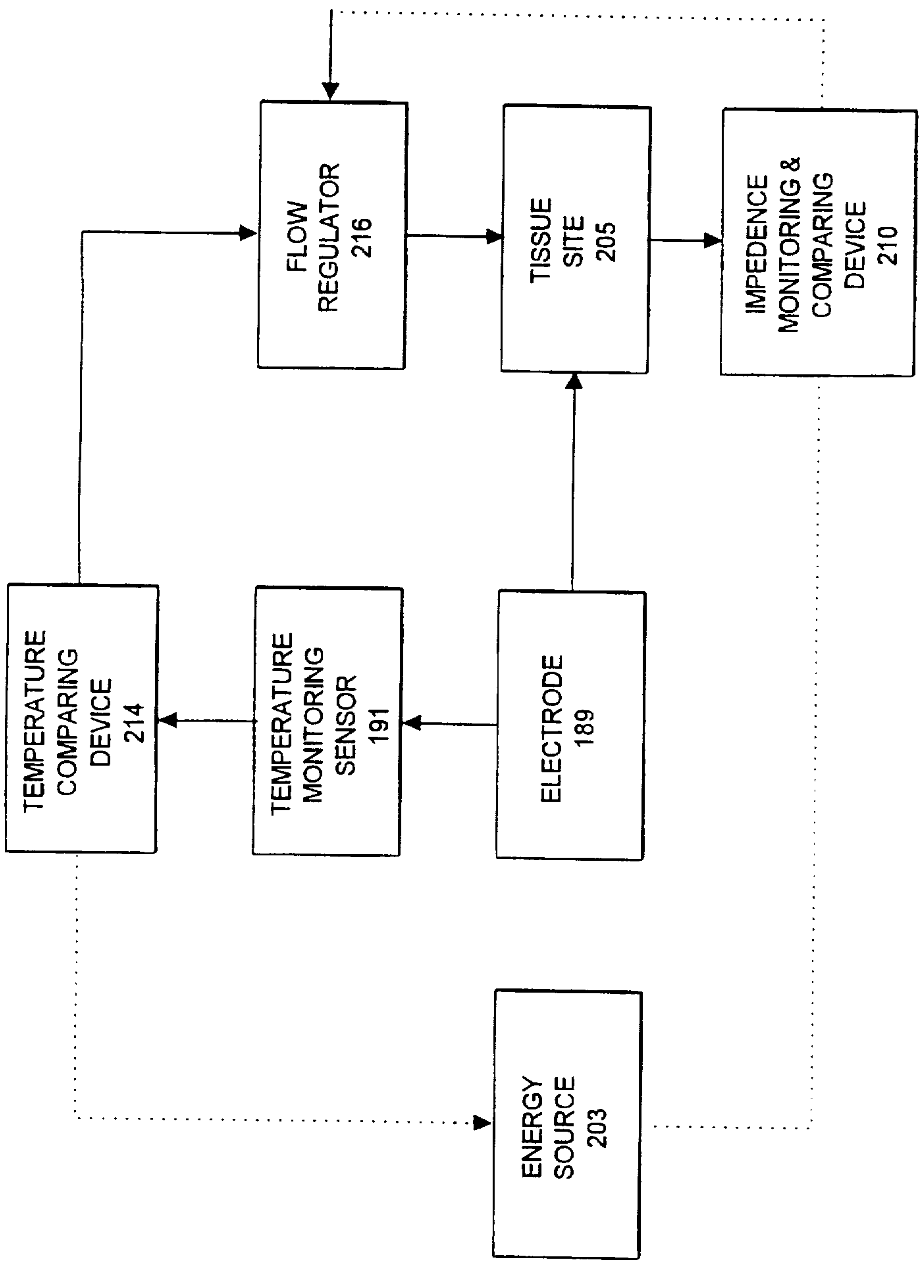
ANALOG
MULTIPLEXER
206
ANALOG
AMPLIFIER
204

FIG. 11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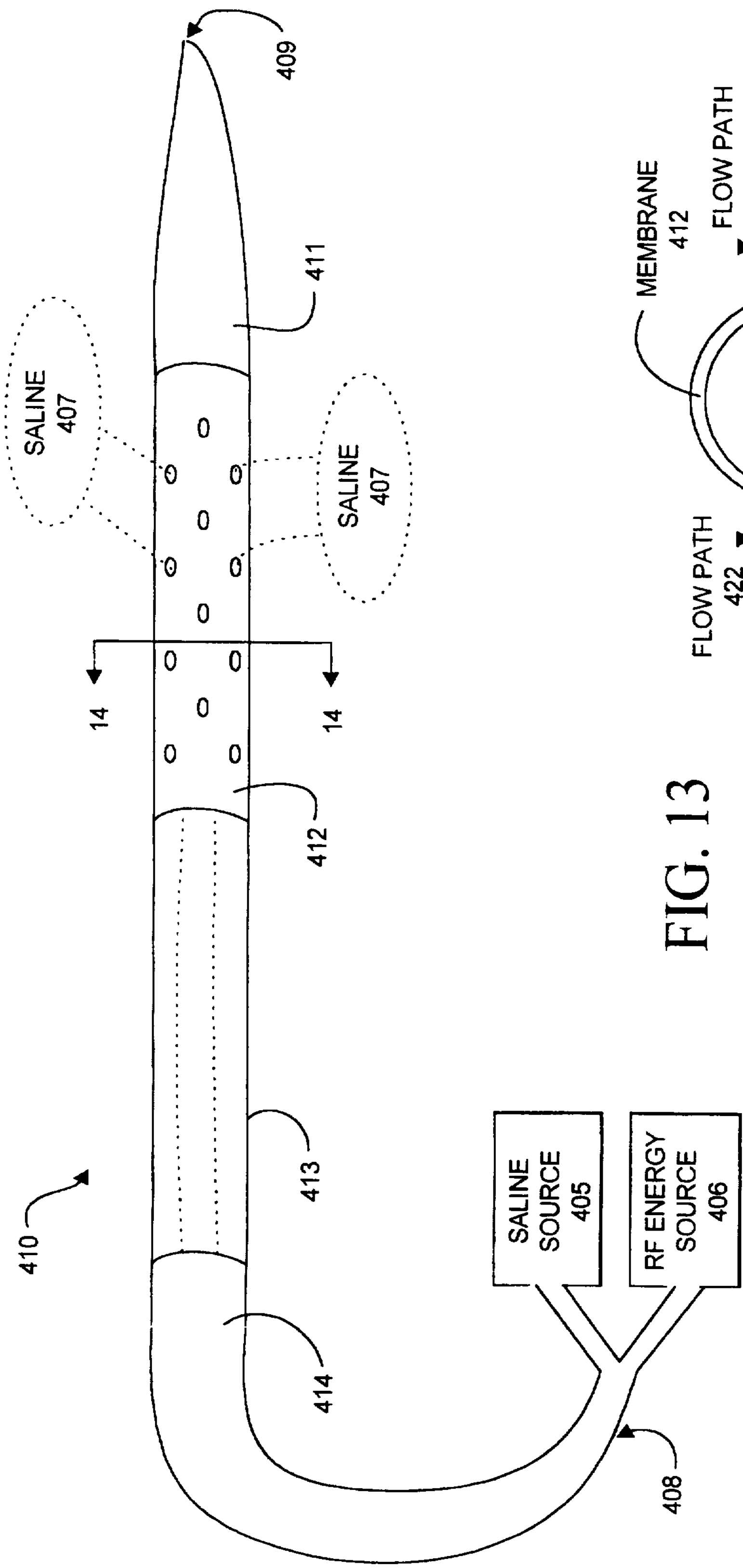
TISSUE SITE 205
IMPEDENCE MONITORING & COMPARING DEVICE 210
TEMPERATURE COMPARING DEVICE 214
TEMPERATURE MONITORING SENSOR 191
ELECTRODE 189
ENERGY SOURCE 203

FIG. 12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SALINE SOURCE 405
RF ENERGY SOURCE 406
408

FIG. 13

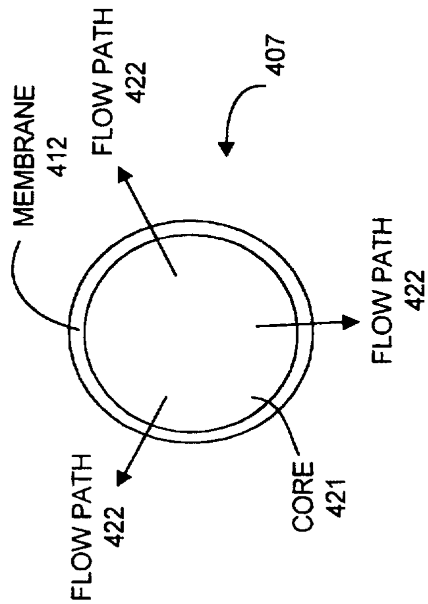
MEMBRANE 412
FLOW PATH 422
407
FLOW PATH 422
FLOW PATH 422
CORE 421

FIG. 14